IN THE UNITED STATES DISTRICT COURT FOR THE

SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION

BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

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CLAUDE R. KNIGHT and CLAUDIA STEVENS, individually and as personal representatives of the Estate of BETTY ERLENE KNIGHT, deceased,

Plaintiffs,

vs. No. 3:15-CV-06424

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Volume 1
Pages 1 through 121

Defendant.
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REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL

WEDNESDAY, OCTOBER 3, 2018, 9:00 A.M.

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Proceedings reported by mechanical stenography, transcript produced by computer-aided transcription.

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CLAUDE R. KNIGHT, Plaintiff

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HUNTINGTON, WEST VIRGINIA

WEDNESDAY, OCTOBER 3, 2018, 9:12 A.M.

THE COURT: Good morning.

MR. CHILDERS: Good morning. How are you?

MS. JONES: Good morning.

THE COURT: Have a seat.

MR. LEWIS: Good morning, Your Honor.

THE COURT: Good morning.

All right. You folks indicated there was at least one issue that remains about openings or something.

MS. JONES: There is, Your Honor. And we were able to work out the other issues. And it relates to a quote that is in one of our slides from an article that I think we agree is a learned treatise. But it would be helpful for us at least to understand what the Court's position is on whether the language that might be used with an expert may be shown on a slide as opposed to going back to the jury with the understanding the rule doesn't permit.

THE COURT: Yes. And the language, I assume, quotes from the treatise.

MS. JONES: It does.

MR. CHILDERS: And my objection, Your Honor, is that this is not being offered during the testimony of an expert. This is the opening statement. I don't believe it's proper to give it to the jury.

THE COURT: Let me see it.

MR. CHILDERS: I'm sorry, I have notes on this so if you will ignore those.

(Pause)

THE COURT: Well, I agree with the plaintiffs on this.

MS. JONES: Okay.

THE COURT: My practice has been to allow counsel to freely use learned treatises in examination of the witnesses, experts in particular, but it doesn't go to the jury. And I think calling attention to it like this outside the context of the witness's testimony is improper.

MS. JONES: And that was -- it will help us for planning purposes -- the same rule should apply for purposes of our closing slides. We shouldn't include quotes from learned treatises.

THE COURT: Yes.

MS. JONES: That's very helpful.

MR. MOSKOW: Your Honor, can I ask just a procedural question? When I'm working with an expert -- when we all are working with experts, will we receive permission to publish the treatise? Even though it's not a full exhibit, it will be marked for identification.

THE COURT: Yes, during your inquiry of the witness about it.

MR. MOSKOW: Yes. And is your practice that we request permission to publish or --

THE COURT: Yes.

MR. MOSKOW: Okay.

THE COURT: Okay?

MR. CHILDERS: Thank you, Your Honor.

MR. MOSKOW: One other issue on the Connolly email that we discussed the other day. There is some further evidence that we'd like to discuss with you. I don't think now is the appropriate time, but perhaps after lunch before the jury comes back maybe --

THE COURT: Okay.

MR. MOSKOW: -- if possible. I know the attorney for the defendants will be arguing it.

MS. JONES: She's here.

MR. MOSKOW: Great.

MS. JONES: Ms. Perez is here.

THE COURT: Is there something I need to see first? Would it be helpful for me to read it or see it?

MS. JONES: They've already shared with us what they plan to submit to the Court, so we're happy to have you have it if it would help you to have that background.

THE COURT: Sure, yeah. Do you want to just give me a brief -- go ahead.

MR. MOSKOW: Sure, Judge. So I have a set of

seven documents that are from, from Boehringer's internal documents. And they reflect an on-going relationship with Dr. Connolly between 2010 and 2014, the period in question, including an invoice from the period August of 2012 through August of 2013.

The email in question, Exhibit 31, is dated July 30, 2012. So I think it's contemporaneous for that purpose and I think it shows a very specific on-going relationship.

THE COURT: All right. I remember the email certainly. Can you remind me of the specific context in which Connolly sent the email? What was it he was conducting or what caused him to send the email?

MR. MOSKOW: If I may, Your Honor, I think it will be helpful to kind of just walk through this. The email is on the back side.

THE COURT: Right.

MR. MOSKOW: And he specifically is referring to -- the subject is the concentration response version for -- with the date. And that specifically refers to the Reilly paper, the concentration paper. And he's saying it's a very nice paper. He ends up being one of the authors on that paper. So he's talking about the paper they're working on together.

And I think what's particularly important about putting this in context is the effect that that statement has on Dr.

Reilly. He responds at the bottom of the first page that he's getting a lot of pressure internally to change those conclusions that Dr. Connolly has said are very nice. And it's that context that we're trying to establish here.

So not only is he a paid consultant and we believe an agent of the company for that purpose, but the email itself has other evidentiary value which is that it had an effect on Dr. Reilly who is writing it.

And, in fact, the response from Dr. Connolly to him saying, "I'm getting lots of pressure," is, "I sort of know that. We'll have to work to find the right dose for the right patient." And Dr. Reilly says, "Great."

So it shows company knowledge. It shows how the company is dealing with these issues. And given what we believe is the significant factual record of an on-going business relationship to the extent that, you know, they're paying him to participate, it meets all of the criteria both to come in for the truth of the matter, but even if the Court were not to allow it for that, it should come in for the effect that it had on the, on the listener.

THE COURT: And the testimony that you've cited where Dr. Reilly, in essence, explains what he did as a result of the Connolly email is part of his testimony that will be at trial?

MR. MOSKOW: So I don't know if I can represent to

you that it's tied up that directly. I think what the record as a whole will show is that there were a series of drafts of the -- what we call the Reilly paper, and that over the course of those drafts the information that Dr. Connolly is talking about here is removed from the paper.

And the ultimate paper does not have a therapeutic range. And that is going to be clearly presented to the jury both through emails and through the testimony, for example, of Dr. Friedman who's likely to testify today by videotape. There's testimony to that effect.

THE COURT: All right. Are you all prepared to respond?

MS. PEREZ: Sure. So in terms of the agency relationship, I mean, again, it is very common for doctors and independent scientists to have consulting agreements with pharmaceutical companies and to be paid for their work with pharmaceutical companies.

THE COURT: Was -- do you know was the work that Dr. Connolly did when he reviewed this version of the paperwork that he performed under his employment relationship with BI?

MS. PEREZ: It was not. And the contracts that are presented here do not cover the date on which this email was written. And that's part of the rule that it must be

within the scope of the relationship and while it existed. And none of the contracts here cover the date of the statement.

So there's no evidence that -- I mean, we would certainly take the position that these contracts do not create an agency relationship even while they were active. But none of these contracts were active on the date the statement was made.

THE COURT: And do you all contest that? I mean, is there something in these documents that contradicts that or --

MR. MOSKOW: So -- and that's why I was clear to say that what we have is an invoice 15 days after the time in question. But I think it significantly contemporaneously -- or it is sufficiently contemporaneous for the Court to infer this on-going relationship, particularly where Dr. Connolly was the lead investigator and the first author of the *New England Journal Of Medicine* article published in 2009, 2010, 2011 talking about the RE-LY trial. He is a named doctor in the Reilly paper talking about re-evaluation of that data.

And there are a series of agreements going from 2010 to 2014 in particular, Your Honor. The document I'm talking about is the last one in your folder which is BIPI PRA0064085920. And it's a one-page invoice from

Dr. Connolly to BI. And he's billing for teleconferences, for data mining, for guidance for data analysis, scientific interpretation.

What's going on here is exactly what we've represented to the Court and that he's being paid for his work in evaluating this data. And it would be, we believe, putting -- we think it would fail to acknowledge the depth and length of that relationship to be looking for a specific document when essentially contemporaneously therewith he's billing for this.

But regardless, and that's why I, I made the point that we are offering this for the effect that it had on the listener and what happened from there. And the effect that it had on the listener here is that Dr. Reilly was continuing to look for the right dose for the right patient. And the evolution of the Reilly paper is something that's an issue for the jury.

THE COURT: Well, based on what I've heard, I'm not inclined to find that Dr. Connolly was an agent of the company for the purposes of this communication. I want to think about your other point.

But if, if you're right and if it's admissible for that limited purpose, then, frankly, I'm concerned that it would be hard to explain to the jury and have them understand the limited purpose for which this email might be admitted.

If -- you've indicated that this email was a factor in the evolution of Dr. Reilly's work such that he ultimately didn't include this discussion. And, so, I'm curious about this. If he -- you can show what he ultimately did and how it evolved. I assume that's part of his testimony that would be admitted.

Why do you need evidence of a statement that would otherwise be hearsay to demonstrate what Dr. Reilly did in reaction to it if you've got the testimony from Dr. Reilly of what he did in reaction?

MR. MOSKOW: Because a central theme of, of the Pradaxa litigation is getting the right dose for the right patient.

THE COURT: Right.

MR. MOSKOW: The Court had a very thorough discussion of plasma concentration and how that fits into the overall claims the plaintiff is making. And we believe the, the role that Dr. Connolly was playing on the one hand, as seen by Dr. Reilly's response to him, and Dr. Friedman on the other, and you'll see he names Dr. Friedman where he says if the paper remains the same, all BI authors have to remove their, their names from the paper, creates a, a scenario that the jury can conclude that the company was putting profits over people.

And, you know, the showing that when true science is

looking at this, Dr. Reilly is saying, "Yeah, we've got to get the right dose for the right people." And when Dr. Friedman is putting pressure on him, the issue is we have to preserve our no monitoring claim. And that's the story I'm trying to tell through -- I'll be putting on Dr. Plunkett either later today or early tomorrow and that's the story we're going to be telling.

THE COURT: Okay. I want to think about it.

MR. MOSKOW: Thank you, Your Honor.

THE COURT: All right. Do you want to say anything in response to close the argument?

MS. PEREZ: Sure. I mean, this email goes to plaintiffs' central substantive claims in this case that there is a therapeutic range for Pradaxa and that patients should be maintained within that range. So, I mean, and I think that's how the jury would take it for the truth of the matter.

And the second point I'd make is just that we expect plaintiffs to present many drafts of the Reilly paper showing how it developed over time, including at one point having a range in the paper and then no longer having a range, and the internal email discussions on that topic.

So whatever probative value this email might have is cumulative of other evidence that we expect.

THE COURT: Okay. Thank you. All right. You

guys are ready to do your strikes when we --

MR. CHILDERS: We are, Your Honor.

MS. JONES: We are, Your Honor. Thank you so much.

THE COURT: Here's generally the course. We'll do the strikes and then we'll take a break, five or ten minutes. We'll let the jurors go in and stretch and have something to drink. Then when we come out, I'll read the preliminary instructions. Then we'll go right into openings.

MR. LEWIS: And then will we do openings back to back or will you have five minutes in between?

THE COURT: I can give you five minutes in between.

MR. LEWIS: To just set up.

THE COURT: Sure.

MR. MOSKOW: And the plan is to get the openings done before lunch?

THE COURT: Yes.

MS. JONES: Thank you, Your Honor.

MR. MOSKOW: Thank you, Your Honor.

THE COURT: Remember jurors will be coming in and we're trying to tell them to sit where they were sitting yesterday. There's not enough room in the jury room. Just be aware of that.

MR. MOSKOW: Can I just ask you, is it your practice that we stand when jurors are entering the courtroom?

THE COURT: I think so, yeah.

MR. MOSKOW: As they're trickling in do you expect us to be standing?

THE COURT: No, only when we're formally in session.

MR. MOSKOW: Thank you, Your Honor.

MR. CHILDERS: Thank you, Your Honor.

(Court and counsel returned to the courtroom at 9:26 a.m.)

(Back on the record at 9:41 a.m.)

THE COURT: All right. I think the remaining juror is on his way up right now.

(Pause)

THE COURT: We just convened, [redacted].

All right. Are the parties ready to proceed?

MR. CHILDERS: Yes, Your Honor.

MS. JONES: Yes, Your Honor.

THE COURT: Is there anything the Court needs to take up before we start with peremptory challenges?

MR. CHILDERS: Not from the plaintiff, Your Honor.

MS. JONES: Nothing for the defense, Your Honor.

THE COURT: All right. My clerk will start

peremptory challenges. We'll start with the plaintiffs.

(Counsel proceeded to exercise their peremptory challenges after which the following occurred:)

THE COURT: All right. The parties have concluded their peremptory strikes. I'm going to ask my clerk to seat the jury.

THE CLERK: Ladies and gentlemen, if I call your name, please step down from the jury box or from the back of the courtroom and just stand in the back for a moment, please.

[redacted]

The remainder of you, if you will fill in the seats closest to this end.

THE COURT: Yes, if you two gentlemen and you lady would all come down to this end. And then those seated come up here and sit. Let's have two of you go to the back row and the other three on the front row.

All right, Madam Clerk, would you administer the oath to the jury.

(Jury panel sworn)

THE COURT: All right. Do the parties have any challenges or other matters they want to raise with respect

to jury selection before I release the remaining members of the panel?

MR. CHILDERS: No, Your Honor.

MS. JONES: No, Your Honor. Thank you.

THE COURT: All right. To you jurors standing, we thank you for your service. You are being excused at this time.

(Remaining prospective jurors excused.)

THE COURT: To you, ladies and gentlemen, you've been chosen as the jury to hear this case, so the next step is going to be we're going to take a little bit of a break and then, not very long, and then when you come back, I'm going to read preliminary instructions to help give you a description of your duties and a brief explanation of what the case is about. And then the lawyers will give opening statements. And then we'll start to hear evidence. So with that, let me give you a couple of reminders.

First, when we take breaks, I'm going to ask you to go into the jury room. If you've been in there, you know this already. If not, you'll see quickly. There are two doors. This outer door and immediately around the back is the women's restroom. On into the conference room there's a second door. And then the men's restroom is around the right side there.

When I excuse you to go to the jury room, keep both

doors closed. I may be conducting proceedings about this that you shouldn't hear, shouldn't be involved with. So please respect that.

When you get back there, as you have already been told, there's a refrigerator with soft drinks and water. There's a coffee maker with coffee. Help yourself to any and all of those things. If there's something else that you think you might need, let us know.

The lawyers will need a few minutes after -- at each of these next steps. I'll do the preliminary instructions. Then we'll take a little bit of a quick recess so the lawyers can set up because I think they're going to use some of the Court's presentation system. But you may have a two or three-minute interruption in between these things for the lawyers to be able to set up. But then we'll move pretty quickly. So with that, you may retire to the jury room.

(Jury retired to the jury room at 9:53 a.m.)

THE COURT: Are there any matters relative to the preliminary instructions that remain at issue?

MR. CHILDERS: Not from the plaintiff, Your Honor.

MS. JONES: No, Your Honor.

THE COURT: All right. We'll take literally about a five-minute recess and see if they need to get something to drink. And then we'll -- as soon as they're ready, we're going to do the preliminary instructions.

And then will you need a couple of minutes after the preliminary instructions to set up or --

MR. CHILDERS: Just -- I mean, it should be very quick, Your Honor.

THE COURT: Well, I guess I should just be clear. Is it going to be such that you want me to excuse the jury or can they just sit here and wait?

MR. CHILDERS: They can sit here. That's fine.

THE COURT: What about when you all start yours?

MR. LEWIS: If we could have a few minutes in between, that would be great.

MS. JONES: We just need to move an easel over to the podium.

THE COURT: Well, then, I don't need to have the jury go into the room.

MS. JONES: I think that's right.

THE COURT: Okay. I'd rather not. If they go in there, I feel like I've got to give them five or ten minutes.

MR. LEWIS: Okay.

THE COURT: All right, a brief recess.

(Recess taken at 9:54 a.m.)

THE COURT: All right. Let's bring the jury in.

(Back on the record at 10:02 a.m.)

THE COURT: If you can remember where you were

seated, it would help us if you went back to that seat. We're going to do a little chart for my staff and for the lawyers. So once you are in your seat, try to remember where it is. We'll ask you to sit there throughout the trial. All right. You may be seated.

All right, ladies and gentlemen, now that you've been sworn, I'm going to give you preliminary instructions to guide your participation in this trial.

First, you are the judges of the facts. You must apply the facts as you find them to the law as I will give it to you in these instructions and in later instructions.

Of course, you must decide this case based solely on the facts as you find them and the law as I give it to you.

You must base your verdict solely upon the evidence presented in this case. The evidence consists of the sworn testimony of witnesses, exhibits introduced into evidence, any stipulations agreed to by the parties, or any matters of which I take judicial notice.

Sometimes the parties stipulate or simply agree that something is true. And in that case, we'll inform you of the stipulation and you may consider that fact to be true.

Also during the trial there are times when I take judicial notice of some uncontestable fact. If I take judicial notice of something, you should consider that fact to be true.

The following are not evidence: My statements and rulings; the attorneys' statements, arguments, questions, and objections; and any evidence that I order stricken or tell you to disregard.

Lawyers have a duty on the part of their client to object if they think there's an improper question or answer. If I sustain an objection to a question, you should disregard that question. If I sustain an objection to an answer, you should disregard that answer.

But if I overrule or deny an objection, you should treat that question and the answer like you do others throughout the trial.

Now, you should consider evidence in the same way you would consider evidence when making any important decision. Feel free to use your common sense. Feel free to draw reasonable conclusions based on your common experience.

During the trial keep an open mind. Do not form or express an opinion about the case until you've heard all of the evidence and my final instructions.

During the course of the trial, the lawyers may refer to direct evidence or circumstantial evidence. Don't be concerned about the difference. Give all evidence, whether it's direct or circumstantial, the weight you believe that particular evidence deserves.

Sometimes evidence is admitted for some limited or

special purpose. Generally when that happens, I will instruct you at the time that that evidence should be only considered for that limited or restricted purpose.

Now, the plaintiffs have multiple claims. All of this arises from the same sort of set of core facts, but there are a number of different legal claims that the plaintiff has brought in relation to them.

Plaintiffs make multiple claims against the defendant in this case, and you should consider each claim separately. If you find a defendant liable on one claim, you need not automatically reach the same verdict as to another claim and vice versa.

Now, the defendant, Boehringer Ingelheim Pharmaceuticals, Inc., is a corporation. A corporation may act only through its agents and employees. In general, an agent or an employee of a corporation may bind the corporation by the acts done or the words said while acting within the scope of authority delegated to that agent or employee by the corporation and while performing his or her duties.

This is a civil case, not a criminal case. In a civil case, a plaintiff must prove every essential element in connection with each cause of action by a preponderance of the evidence, not beyond a reasonable doubt.

Now, I'll give you more detailed instructions about the

law surrounding the claims involved at the end of the case. But to help you understand and follow the evidence, I want to give you a brief summary of what the plaintiffs must prove to make their case in connection with each of the causes of action, each of the claims.

Plaintiffs claim generally that Pradaxa, which is a drug that was sold by Boehringer -- and I'm going to use the initials BI frequently for them -- that the drug Pradaxa sold by BI injured Ms. Knight and caused her death.

Plaintiffs' case is based on five separate claims against the defendant. These claims are as follows:

First, that the warnings provided with Pradaxa were inadequate;

Second, that BI failed to exercise reasonable care in formulating the warning for Pradaxa;

Third, that BI breached an express warranty covering Pradaxa;

Fourth, that BI breached an implied warranty covering Pradaxa;

And, fifth, that BI committed fraud by misrepresenting facts related to Pradaxa.

Now, of course, BI denies any failure to warn, any negligence, any breach of warranty, or any fraud on its part, and denies that it engaged in any wrongful conduct that caused her death. BI further asserts that Ms. Knight's

death was due to other causes.

So I will instruct you and explain the law regarding each of these claims separately. And then you will consider and decide each claim separately when you get to that point in your deliberations.

First, part of the claims here are brought under the theory, legal theory called strict liability. Plaintiffs, Claude Richard Knight and Claudia Stevens, those are the adult children of Mrs. Knight, individually and as personal representatives of the estate of Betty Knight, deceased, claim that Betty Knight was injured by a defect in Pradaxa manufactured and sold by Boehringer.

To recover, plaintiffs must prove by a greater weight of the evidence all of the following:

First, that BI distributed, manufactured, and sold Pradaxa;

Second, that Pradaxa warnings were defective when the product left BI's possession;

And, third, that Pradaxa's defective warnings were a proximate cause of Betty Knight's injury, including her death.

Now, the plaintiffs claim that Pradaxa was defective because its warnings of potential risks and side effects were inadequate. In considering this claim, you are instructed that not all dangers require warnings. You must

decide what a reasonably prudent manufacturer would have done in regard to the safety of Pradaxa at the time of its manufacture. To establish this claim, the plaintiffs must prove each of the following elements:

First, that BI manufactured, distributed, or sold Pradaxa;

And, second, that a use of Pradaxa which was reasonably foreseeable to the manufacturer involved a substantial danger that would not be readily recognized by the ordinary user of Pradaxa;

And, third, that BI failed to give adequate warnings of that danger;

And, fourth, that BI's failure to provide adequate warnings was a proximate cause of Betty Knight's injuries, including her death.

Now, BI may be liable for failure to warn only if a warning would have made a difference. Plaintiffs must establish that the warning suggested by them would have caused Betty Knight to act differently or otherwise change her behavior in a manner that avoided the injury.

If a warning by a manufacturer would not have prevented Betty Knight's injuries, including her death, then you may find in favor of BI.

The next claim brought is a claim under negligence. In addition to her claim -- their claim that Pradaxa was

defective by virtue of inadequate warnings, plaintiffs also claim that BI was negligent by not using reasonable care to warn about Pradaxa's dangerous condition or about the facts that make Pradaxa likely to be dangerous.

To establish this claim, plaintiffs must prove by a greater weight of the evidence the following:

First, that BI sold Pradaxa;

And, second, BI knew or reasonably should have known that Pradaxa was dangerous and likely to be dangerous if used in a reasonably foreseeable manner;

And, third, that BI knew or reasonably should have known that users would not realize the danger;

And, fourth, BI failed to warn adequately of the danger of Pradaxa;

And, fifth, that a reasonable seller under the same or similar circumstances would have warned of that danger;

And, sixth, that Ms. Knight was injured;

And, last, that BI's failure to warn was a proximate cause of Ms. Knight's injury, including her death.

Negligence is the failure to use reasonable care. A seller is negligent if it fails to use the amount of care and warning about a product that a reasonably careful seller would use in similar circumstances to avoid exposing others to a foreseeable risk of harm.

In determining whether BI used reasonable care, you

should balance what BI knew or should have known about the likelihood or -- and seriousness of potential harm from Pradaxa against the burden of taking safety measures to reduce or avoid that harm.

The next claim brought by plaintiffs is under an express warranty theory. Here the plaintiffs claim that Betty Knight was injured by Pradaxa because BI represented to Betty Knight that -- represented that Betty Knight could safely use Pradaxa which was not true. To establish this claim, plaintiffs must prove the following:

That Betty Knight purchased the product;

That BI made a statement of fact to Betty Knight that Pradaxa was safe for her;

That Pradaxa did not perform as stated;

That Betty Knight was injured;

And that Pradaxa's failure to perform as BI represented it would was a substantial factor in causing Betty Knight's injury, including her death.

The exact words "warranty" and "guarantee" are not required to create an express warranty. It is also not necessary for BI specifically to have intended to create a warranty. However, a warranty is only created if you find that BI made an affirmative representation concerning the safe use of Pradaxa.

The next claim is under implied warranty. Here the

plaintiffs claim that Ms. Knight was injured because -- by Pradaxa because the product did not have the quality that a buyer would expect. To establish this claim, the plaintiff must prove these elements:

Again, that Betty Knight purchased the product;

Next, that at the time of purchase, BI was in the business of selling Pradaxa;

Third, that Pradaxa was not fit for the ordinary purposes for which such goods are used and/or it did not conform to the promises or affirmations of fact made in the label or Medication Guide;

And that Betty Knight was injured;

And, last, that the failure of Pradaxa to have the expected quality was a substantial factor in causing Betty Knight's injuries, including her death.

The next cause of action is under the claim of fraud. To prevail on a claim of fraud, the plaintiff must prove each of these elements:

First, that BI committed an act that was material and false;

That Ms. Knight relied on that act;

That Ms. Knight was justified under the circumstances in relying upon it;

And that Ms. Knight was damaged because she relied on it.

In the fraud claim plaintiffs must prove each of these elements by clear and convincing evidence, a higher standard of proof than just preponderance of the evidence.

Now, in the course of the trial evidence may be introduced that Pradaxa -- that the Pradaxa sold by BI complied with certain federal and state laws or administrative regulations.

When you are determining the issue of failure to warn, negligence, and breach of warranty, you may consider BI's compliance with any federal or state law or any administrative regulation that prescribed standards for the manufacture of Pradaxa existing at the time that Pradaxa was manufactured. Compliance with appropriate regulations is competent evidence that BI exercised due care in marketing Pradaxa.

Now, if you decide that the plaintiffs have proven that BI was legally responsible for Betty Knight's injuries or death, you may reasonably compensate plaintiffs for any harm that Betty Knight suffered. The purpose of awarding damages is to compensate a person who has been injured or harmed as fully and completely as possible.

Damages that are speculative cannot be recovered. However, the mere fact that damages may be difficult to determine should not cause you to refuse to award them where the right to such damages has been proven.

You may award the following specific items of damage if you find that they've been proven by a greater weight or preponderance of the evidence:

Betty Knight's past physical pain and suffering, mental anguish, disfigurement, emotional distress, loss of enjoyment of life.

There's no rule or set method for deciding the amount of these types of damages. The amounts are left to your discretion to decide whether it's fair and just. You must use your judgment to decide a reasonable amount based on the evidence and your common sense.

The next element of damages that may be considered if proven would be Betty Knight's past reduction of her ability to function as a whole person. And to recover here the plaintiffs must prove that the injury deprived or reduced Betty Knight's ability to participate in her customary activities and resulted in the loss of enjoyment of life.

Again, there is no rule or set method for determining this amount -- this type of damage. It's left to your discretion to decide based on what's fair and just. And you should use -- you should decide any reasonable amount based on the evidence and your common sense.

Another element of potential damages would be Betty Knight's past medical expenses. To recover past medical expenses, the plaintiffs must prove the reasonable cost of

reasonably necessary medical care that Betty Knight received.

Medical bills introduced are to be considered reasonable and necessary unless you find that BI has proven that these medical bills were not reasonable in amount or necessary for the medical care of Ms. Knight.

If you decide that BI is legally responsible for the death of Mrs. Knight, then you may award additional and different damages.

Here you may award the plaintiffs as administrators of her estate damages for expenses reasonably incurred as a result of Ms. Knight's death.

Expenses incurred by administrators may include damages such as reasonable funeral expenses, reasonable hospital and medical expenses related to the injuries suffered by Ms. Knight that resulted in her death, and any other expenses reasonably incurred as a result of the wrongful conduct that resulted in her death.

In addition, you may award damages to the administrators that you find are fair and just to reasonably compensate Claude Knight and Claudia Stevens, her adult children who are the administrators. You will decide the amount of damages to be distributed, if any, to each of these persons.

In making any award of damages to be distributed to

each of these persons, you may consider the sorrow, mental anguish, and solace suffered as a result of her death. This may include loss of society, companionship, comfort, guidance, kindly offices and advice of Ms. Knight.

Second, compensation for any conscious pain and suffering that Ms. Knight suffered between the time she was injured and the time of her death. To award damages for pain and suffering, there must be evidence that Ms. Knight was conscious of the pain and suffering prior to her death. Where there is no evidence that she consciously perceived pain and suffering, no damages for pain and suffering could be awarded.

Last I want to talk to you about your conduct as jurors during this trial.

First, as I've told you throughout, do not discuss this case with anyone or allow anyone to discuss the case with you or around you during the trial. If anybody tries to do that, please bring it to my attention promptly.

I know that everybody has a cell phone these days and other sorts of technology. When I instruct you about not communicating about the case, it includes any sort of communications on any of these social networking sites, on the internet, or anything like that.

Do not read any news stories or articles or listen to any radio or TV coverage about this case or anyone who has

anything to do with it. Do not investigate or research or look into anything about this case on your own.

You've got to decide this case together based solely on the evidence that you hear in the trial and my instructions. So please refrain from trying to look up anything on the internet or any other source about any of the matters pertaining to this case.

Do not make up your mind about what the verdict should be until you've heard all of the evidence, my instructions, closing arguments, and then you go in together to deliberate about the case. Keep an open mind until then.

Now, generally I tell jurors not to try to take notes. But this is going to be a lengthy trial, as you already know, and may involve some fairly complicated medical and similar evidence. So I'm going to give each of you a notepad and a pen.

If you want to take notes, you may. Do not feel obligated to take notes. What's most important, of course, is that you listen to the testimony and the evidence and then discuss it together. That's the best way to have a grasp of what that evidence entails.

Also, many people are used to taking notes in everyday life or in their work. If you're one of those people and it helps you, then you should do it. Many people do not engage in that. And if you aren't somebody who regularly takes

notes or writes things down, it might be more of a distraction than a help for you to try to keep up with things by making notes. In any event, I leave it to each of you in your own judgment to decide whether you want to take notes.

If you decide to take notes, I further instruct you and your fellow jurors that those notes are for the individual juror's use only. No other juror should rely upon someone else's notes in determining what the testimony was. I would instruct those of you who take notes to keep those notes to yourself and for your own use only.

Also, you know we have a court reporter here. She will be taking down everything. But we will not have any sort of transcript available for you when you start to deliberate to recall more specifically what witnesses say.

The only transcript that jurors could use for something like that would be an official transcript. And it takes weeks for the court reporters to do an official transcript. They have to -- like two court reporters taking turns with this, they have to review their notes, their recordings, go over things. And it takes a lengthy time to make sure that it's absolutely accurate. And until then, that transcript couldn't be used by a jury. So do not expect that I can provide you with a transcript of any witness's testimony.

If you all listen carefully and talk together about

what you understood the testimony to be, I'm sure you can come to a common understanding and agreement about what that evidence is. So do not expect that we can have a transcript.

As I reminded you, when you're in here in the jury room, please keep both the doors shut.

We're now going to start the trial. The first step will be each side's lawyer will be able to make an opening statement.

An opening statement is merely an outline by the lawyer to help you understand how the evidence is expected to come in according to that party. An opening statement is not evidence and it's not argument about the verdict.

After opening statement, the plaintiffs will introduce evidence in support of their claims. If they call a witness, the defense gets to cross-examine that witness. After the defendants present their case -- after the plaintiffs present their case, the defendant may offer evidence calling its witnesses. Plaintiffs' lawyers will cross-examine those witnesses.

After the defense presents any evidence, the plaintiff has -- which has the burden of proof, has the final opportunity for any rebuttal evidence.

At that point, all the evidence will be in. I will then instruct you on the law that you're to apply. I know I

gave you lengthy instructions just now about each of these claims. Don't be concerned about trying to memorize any or all of that. I will give you those instructions again at the end with actually a little more explanation, and probably at that point even give you a copy of the instructions that you can refer to during your deliberations.

But don't be concerned about not fully recalling each of these things. No one can do that. It was just intended to help you have a frame of reference about the evidence you're about to hear. But once we get to that point, you'll be in your deliberations and that's when you should decide this case.

So with that, are you ready to make your presentation?

MR. CHILDERS: If I could just have a moment.

THE COURT: All right. My clerk's going to pass out these pads and pens. As I've said, feel free to take notes. And if you are a note-taker and you decide you need something larger to write on, just let us know and we'll get a bigger legal pad. We weren't sure how many of you might want to take notes or how easy it would be to take notes on that.

Also, as they're setting up, we have a presentation system in the courtroom that utilizes all of these things connected. So you'll see monitors on the front. So those

monitors, this TV and the larger TV here all show the same thing.

When an exhibit is introduced into evidence, it will be shown, most likely, on the monitor. And then some exhibits will be physically passed to the jury. So you can expect to look at any of these.

If you have trouble seeing anything, just give me a sign. Raise your hand and tell me. We'll make sure things are working right and they're showing up right.

MR. CHILDERS: Thank you, Your Honor.

I'm not used to wearing one of these lapel mics, so I apologize.

Drugs can hurt people. We all know that. We talked about this at length yesterday, that any time you take a medication, you take a risk. Because drugs can hurt people, drug companies who sell them have some specific duties to patients.

What does a drug company have to do? In order to avoid liability for injuries to a patient, they only have to do one thing. They have to warn the patient about the side effects that that drug can cause.

If they don't warn the patient or if they don't adequately warn the patient, then they can be liable and they are liable for failing to warn.

You heard the Judge give you a lot of instructions just

a few minutes ago about all the different claims that the plaintiffs are making in this case. It really boils down to that, failure to warn.

The drug company had information that should have been given to Betty Knight and her family and it wasn't. And that's what the evidence is going to show.

My name is Andy Childers. We met briefly yesterday. I got to speak with some of you. I appreciate all of your openness, your willingness to serve as jurors in this case. I know it's not easy. I know it's a hardship. But we greatly appreciate that because this is a very important case.

It's a very important case to Rick and his sister Claudia who you met yesterday and the rest of their family. And we -- all we ask is that you listen with an open mind, that you pay attention, and that at the end of the day, you return a just verdict.

I want to also introduce you to Neal Moskow who you met yesterday. He's going to be sitting here with me pretty much every day through this trial. You're going to hear from him later hopefully this afternoon, possibly tomorrow. And there will be a few other people you may hear from our side as well.

The issue that we're going to address here is warnings to patients. What you may hear in the case is warnings that

were given to Betty Knight's doctors. That's not the law in West Virginia.

The West Virginia law is a drug company must warn the patient directly. It's not enough just to tell their physician. You have to tell the patient so that the patient can make an informed decision as to whether or not they actually want to take that drug.

We heard a lot yesterday about atrial fibrillation. I think most of you guys knew what that was or you at least had heard of it. I want to just real briefly talk about it again just so we know we're all on the same page, at least starting on the same page.

All that is is an irregular heartbeat. The heart doesn't beat quite normally. And because of that, the chambers in your heart, some of the blood stays up there a little longer than it should and you can get a blood clot.

Because of that, people take anticoagulants. We talked a lot yesterday about anticoagulants too. The anticoagulant does not cure atrial fibrillation. It actually doesn't affect the rhythm of the heart at all. All it does is thin the blood.

When we say anticoagulants, we're talking about blood thinners. I'll probably use those two terms back and forth. I prefer blood thinners, but the scientific term is anticoagulants. So you'll hear me say both.

For about 50 years, more than 50 years when people had atrial fibrillation, they took a drug called warfarin. It's also called Coumadin. I think most everybody here had heard of that yesterday as well.

Coumadin was what we call the gold standard for atrial fibrillation. People took it. When you take Coumadin, you have to have your blood monitored. The blood is monitored to make sure it's not too thick, it's not too thin. If it's too thick, it's not helping you. You could still get a clot. If it's too thin, you're going to be too likely to have a bleed and that's not safe.

And, so, when a patient is on warfarin or Coumadin, they go see their doctor. They go to what we call a Coumadin clinic or maybe they just go to the doctor's office. They have their finger pricked. They check their blood level. And they decide either the medicine is just fine the way it is or we have to increase the dose or we have to lower the dose. And they do that on a regular basis to make sure they stay safe.

Because that was the only drug on the market for blood thinning for atrial fibrillation patients for so many years, drug companies saw an opportunity. If they could make new blood thinners that didn't require patients to go see their doctor on a weekly basis or a bi-weekly basis or a monthly basis, then they could potentially tap into this market.

There are millions of people who have atrial fibrillation. It's more common in older patients. As the population of this country ages, more and more and more people have atrial fibrillation. So this is a giant market for pharmaceutical companies.

The company that we're here to talk about, the company that we've sued in this case is called Boehringer Ingelheim.

And I'm sorry. Am I standing in front of this so you all can't see? Okay.

They're a company based in Germany. They're a family-owned company, which is quite unusual for a pharmaceutical company. They've been around for over 100 years and they're owned by the Boehringer family.

This company does also have an office here in the United States in Connecticut. They decided that they would try to get into this market, the atrial fibrillation blood-thinning market. And what they came up with was the drug called Pradaxa.

Pradaxa is different from warfarin. It works differently. It's called a direct thrombin inhibitor. I don't expect anybody to know what that means. All it really boils down to is it affects one specific part of the way that your blood works to try to make it a little bit thinner. Okay?

And you're going to hear more about that. There are

going to be some doctors and other folks who come to explain it better than I can. But the whole essential way that this drug works, it thins your blood.

Not surprisingly, because this market was so big, there was more than one drug company that was trying to come up with an alternative to warfarin at the exact same time.

As you know, when you have a particular ailment, there's usually four or five different drugs you can take and they're all made by different companies. That's called a class of drugs. And that's what happened here.

There was Xarelto being developed. I think a lot of folks yesterday had heard of Xarelto. There was Pradaxa being developed, and a drug called Eliquis were all being developed at the same time.

But because there was no competition yet, they all knew that the first one to get to market was going to have a leg up on the competition. If you're the first one there in a market that has never had a non-monitored drug to use to thin blood, people are going to want to try it. Doctors are going to want to try it. You're going to make money if you're the first one to get there.

And that's exactly what happened here. Pradaxa got to the market first. They beat the competition to the market.

You're going to hear some testimony from Boehringer's employees. This is a group of them. You will hear from

some, maybe all of them during the course of this trial. They don't live here in West Virginia. Because of that, we can't force them to come into the courtroom and testify.

So we have taken their depositions. We've gone to wherever we needed to go to do that and recorded those depositions so that we could play them here for you at trial.

That is not exciting. It is not exciting to watch videotaped testimony of witnesses, especially some of these folks who speak other languages and it has to be translated.

We have tried our very hardest to edit them down to limit the amount of time that you'll have to watch these videos. But we have to give you this essential information.

And, so, as boring as that may be, I just ask please try your hardest to pay attention because those are going to be the hardest days, hardest parts of this trial is to pay attention to these witnesses on these videotapes that we play for you.

But remember when we play those tapes, they've been sworn in, just as you'll see witnesses who come in here and testify. They've sworn to tell the truth just like they were here in court. So their testimony has the same weight as it would have if they were here live. And I apologize it's going to be a little boring, but we're going to try to move through it as quickly as we can.

Because we're going to start out -- and we're going to start out right after the opening statements with a video of one of these folks. I wanted to go over briefly some of the terms you're going to hear.

I don't expect you to remember all these, but I wanted to start by going over some of them with you. You're going to hear more about them from our expert witness, Dr. Plunkett, who will be here either later today or tomorrow.

But some of the things you're going to hear are words like anti-platelets, aspirin, and Plavix. If you'll just remember aspirin and Plavix are anti-platelets, that's all you need to know. They help to also keep your blood moving.

Anticoagulants. We've talked about those already. Pradaxa, warfarin, Eliquis. They thin your blood. Anticoagulants are blood thinners.

Here's one. If anyone here has ever heard of it, I'll be shocked. It's called P-gp inhibitor medications. And I'll be honest with you. Before I got involved in this case, I'd never heard of that before.

That's a class of drugs that affects the way Pradaxa and other medications actually get into your system. So if you're taking another drug that happens to be a P-gp inhibitor, it affects how much Pradaxa you get in your system. And you'll see that that becomes very important

because the amount of Pradaxa you have in your system affects how thin your blood is.

Pretty simple, just like warfarin and Coumadin. The more you have, the more likely you are to bleed. The less you have, the less likely it is to help prevent a stroke or a clot.

And you're going to hear about P-gp inhibitor medications that Ms. Knight was taking in this case when she was taking Pradaxa.

Here's a word, "hemoglobin." That comes up a lot. If you've ever gone to the hospital and they checked your blood level, they checked your hemoglobin. It has to be a certain level for you to be healthy.

If it gets too low, you're not getting enough oxygen into your body. That's the part of your blood that takes oxygen from your heart and takes it around to the rest of your body.

So when it gets too low, it's called anemia. I'm sure you've heard of that term as well. But you're going to hear it here as well.

You're going to hear us say the word "plasma" a lot. That's just blood. Plasma is blood. But plasma is the way that a lot of these witnesses refer to blood and the amount of Pradaxa. They'll say a plasma concentration. All they're talking about is how much Pradaxa is in your blood.

You're going to hear the term "trough concentrations." What the heck is that? Trough concentration means when you take a medicine -- this is a twice-a-day medication that you take. When you take it, you hit a peak and your body starts to metabolize it and it goes down.

Right before you take your next dose, that's called the trough, meaning it's the lowest amount of drug you have in your body while it's active. Okay? That's important because in this case, the way that a doctor, if they're instructed as to how to measure the Pradaxa level in a patient, does that is by measuring the patient's trough Pradaxa concentration.

Everybody thoroughly confused already? Okay.

We're going to hear about blood tests. You're going to hear a lot about blood testing. There are several different blood tests. But you're going to hear them referred to by letters, aPTT. That tells how fast your blood clots. That's all that is. It's telling you how many seconds it takes for your blood to clot when they test it in the lab.

You're going to hear dTT, same thing. It's just a different kind of test.

INR. You may be familiar with that. That's the test they use to find out how warfarin is affecting a patient's blood. It's not helpful for Pradaxa, but it's used with warfarin.

And then there's one other test called ECT, same thing. They're just trying to figure out how fast does your blood make clots. How thin is it? How thick is it?

We're going to talk about strokes in this case. We talked a lot about strokes yesterday. There's two different kinds of strokes.

Ischemic stroke. You'll see that term. That's when you get a clot that gets in a blood vessel. So it sort of clogs up the blood vessel and then the blood doesn't get to where it needs to go.

And then there's something called a hemorrhagic stroke. That's where a blood vessel actually breaks or tears and blood spills out. If that happens in the brain, it's called a hemorrhagic stroke.

And another term that is probably new to all of you is NOAC. You're going to hear that over and over and over again. That's this class of drugs, the Xarelto, the Pradaxa, the Eliquis. They're called the NOACs because they're new oral anticoagulants. All you have to remember is NOAC is Pradaxa. The old oral anticoagulant is warfarin.

Okay. Sorry about all that. As we were talking about before, with any anticoagulant, the more you have, the more likely you are to bleed. The less you have, the more likely you are that you're going to have a clot.

So it's important to be able to maintain a balance with

the amount of anticoagulant you have no matter what that anticoagulant is.

The evidence in this case is going to show that Boehringer Ingelheim knew that, that that was true for Pradaxa just like it's true for any other anticoagulant.

But the evidence is also going to show that Boehringer knew if it was like Coumadin, that you had to check it. Doctors aren't going to prescribe that. It's a new drug. New drugs cost more. They're not tested as well as the old drugs.

If a patient has to be monitored, if they're going to have to come in and have their blood checked on a regular basis, well, that sounds a lot like Coumadin. It sounds a lot like warfarin. How are they going to convince people to take this new drug if it sounds like they're taking the one they're already used to?

And you're also going to hear that internally the company knew that if there was monitoring involved with Pradaxa, it would kill sales. You can't sell this new class of drugs if you tell doctors and patients, "You've got to keep getting your blood monitored just the way you are now."

Let me go back to that just for a minute. The evidence is going to show that we know Boehringer knows this. We know Boehringer knows how to do this as well, how to monitor blood, and how much is too much.

And the reason we know that and the reason we know that they know that is, as you will see, they tell doctors in other countries exactly that information. They don't give that information to doctors or patients in the United States. That's the evidence you'll see here.

You're going to hear later today hopefully from Dr. Laura Plunkett. She's an expert in pharmacology, toxicology, and drug labeling. She's got a Ph.D. in pharmacology. She's a certified toxicologist. She advises drug companies on what information needs to be in drug labels.

She is involved in litigation as well. That's why she's here with us. And you'll hear a lot about that in other cases, I'm sure, that she's testified in. She'll be asked about that when the defendants cross-examine her.

The reason she testifies in these cases is because she's an expert. And she knows what the rules are and she knows what drug companies are required to do. And she knows when they don't follow those rules. And that's when she steps in and acts as an expert witness in cases like this.

She's going to tell you or explain to you with Boehringer's own documents and Boehringer's own testimony that they know in patients who are healthy patients, in healthy patients, one in five of them that you give a pill to is going to either have too much or have too little.

That person is going to be in either danger of a stroke or danger of a bleed. Twenty percent of the people they give this pill to, they're going to be out of range.

She's also going to tell you -- she's also going to tell you, though, that Boehringer doesn't tell doctors in the U.S. or patients in the U.S. how to figure out if they're that fifth person. How do you know if you're the one in five who has too much or too little? You don't. You take the pill, hope for the best, even though they know how to figure that out.

We talked a lot yesterday about speaking to your doctor about medications, talking to them about what are the pluses and minuses, the risks and side effects.

We talked a little bit about drug ads on TV. Not too many of you seemed to recall any. There are ads on TV. Drug companies advertise their products, TVs, magazines, what have you. And when you see those ads, they inevitably tell you some information about the product. And at the end they say, "Ask your doctor about this drug."

What you're going to hear in this case is that's what happened. Claudia, Betty's daughter, saw on TV in 2011 a Pradaxa television commercial. She knew her mom was on warfarin. She knew her mom had to go get her blood checked on a very regular basis. She knew her mom had to kind of watch what she eats, couldn't eat salads or greens.

And she -- when she saw that ad, what she took from it, as you will hear from her, was Pradaxa is more convenient than warfarin. You don't have to go in and have your blood checked with this drug. You can eat salads with this drug.

And, so, what she did, she told her brother Rick, "Hey, Rick, I saw this ad. Do you think this is something that might be good for mom?"

And the evidence will show Rick called Betty's doctor's office, Dr. MacFarland's office, left a message, and said, "We want to talk about switching mom to a different blood thinner."

And the evidence will show that the three of them, the three of them went together to Dr. MacFarland's office in October of 2011 and they sat down with her nurse.

It's important for you to know too, and you'll hear this in the evidence, Dr. MacFarland had been prescribing warfarin and managing warfarin for Betty Knight for six years at that point.

She had a lab in her office where patients would come in to have their blood drawn. And they wouldn't just see a blood-drawing person or a tech. Dr. MacFarland herself would come and see the patient every single time they went in to have their blood drawn.

Think about that. You've got a sick patient, an elderly patient who's coming in to have her blood drawn and

is being seen and talked to and evaluated by their doctor every single time.

Dr. MacFarland will tell you that's a pretty good idea. If a patient is sick, what's better than having a doctor actually see them more?

But with Pradaxa, that doesn't happen. You don't go to the doctor to have your blood drawn anymore and you see the doctor less and less.

And, so, what the evidence will show is that that day when they went in to see Nurse Clagg at Dr. MacFarland's office, they talked to her about it. They said, "Hey, we saw this ad. Do you think this will work?" And she said, "Let's give it a try."

And it's important to know they put her on a dose that is 75 milligrams. You're going to hear there are two different doses of Pradaxa, 150 milligrams and 75 milligrams.

The 150-milligram dose is what they tested in their clinical trials along with a dose of 110 milligrams that they don't sell here in the U.S.

The clinical trial didn't involve the 75-milligram dose. But that's the dose that they worked out with the FDA that they would sell to patients who have severe kidney impairment, people whose kidneys don't work very well. And they don't -- they really don't work very well; patients who

are not on dialysis but they're not that far away either.

That's important because you'll hear, and the evidence in this case, Pradaxa, when you take it, it clears through your kidneys, meaning when you take anything in, you ingest it, you metabolize it, and then you excrete whatever is left.

With Pradaxa, it goes almost all through your kidneys. The worse the function in your kidneys are, the more and more and more the medication builds up in your system because it's not getting out. That's why it's so important to make sure a person with impaired or bad kidneys doesn't have too much Pradaxa in their system.

And you'll see in this case -- and I'm sorry this is so small. We don't have to get into the details of it right now. But this is the Medication Guide that was given apparently from the pharmacy. You'll hear the pharmacy's giving these Medication Guides to patients when they fill medications. I think we talked about that yesterday. They staple them or they put them in the bag.

This is the warning that Boehringer gives to patients. This is the entirety of it, these four pages. And what you're going to hear, this is where kind of the rubber meets the road. This is where the warning issue comes to light in this case. Did they warn Betty and her family adequately or not? That's your decision to make.

We're going to present to you evidence to show that there were several things they failed to tell Betty and her family that would have absolutely prevented them from switching her to Pradaxa from warfarin. And let me back up a minute on that too.

Betty was on warfarin a long time. Sometimes her levels got too high. Sometimes her levels got too low. But because they checked it on a regular basis, they were always able to get her back where she needed to be.

And you'll hear Dr. MacFarland testify herself. She never had a bleed and she never had a stroke while Dr. MacFarland was managing her warfarin.

You'll hear also from Dr. MacFarland it wasn't her idea that Betty needed to change to another drug. The family came in and asked for it because they saw a TV ad, a commercial, that said, "Ask your doctor about Pradaxa."

And, so, what we're going to show you with this Medication Guide is there are several pieces of information missing that the patient should have known; and that if the patient and her family would have known, they never would have switched her to Pradaxa from warfarin.

First and foremost, this drug, Pradaxa, had never been tested in patients who have severe renal impairment. That's Betty Knight. She had severe renal impairment. They excluded those patients from their clinical trial.

Why did they do that? Because it's dangerous. But when they sold this drug to Betty Knight and her family, they didn't tell her that. They didn't tell them that. They didn't say, "Hey, by the way, we haven't actually tested this drug in a patient like you. You need to know that before you agree to go off the medication that's been working for you for the last six years."

The second thing they never told patients, or they didn't tell Betty Knight and her family, excuse me, this 75-milligram dose that she took, it had never been tested in a human patient at all, at all.

They ran some computer simulations based on the testing they did in healthier patients who were taking the 150-milligram dose and came up with a dose that they never tested in patients.

Instead of doing a clinical trial, they made Betty their clinical trial. But they didn't tell her that. That's the failure to warn.

Can you imagine taking a drug that had never actually been tested in human patients and not even knowing it? That's failure to warn.

The third thing they didn't tell Betty and her family was, "Don't take Pradaxa and Coreg." Because she had severe renal impairment, she shouldn't have ever taken those two drugs together. They'll tell you that. Coreg is a P-gp

inhibitor. We talked about that a few minutes ago. It causes the Pradaxa to -- it causes more of the Pradaxa to get into your system.

And, so, Betty was on Coreg already. They didn't tell her or her family, "Because you're on Coreg, this is not the medication for you. Just stick with what you have. It's working for you. Stick with that." They didn't do that. They never told her that.

The fourth thing that they didn't tell Betty and her family was that, "If you have a bleed on Pradaxa, there's nothing we can give you to stop it. There's no reversal agent."

If you have a bleed and you're on warfarin or Coumadin, they give you Vitamin K or they can give you what's called fresh frozen plasma and that helps to stop it.

Betty and Rick and Claudia knew that because on occasion when her levels got too high, she would take Vitamin K and it worked. But you know what they didn't know? If that happened on Pradaxa, you're just going to have to wait that bleed out and hope for the best.

The fifth thing that Boehringer didn't tell her or her family was that when you take Pradaxa, you're much more likely to have a GI bleed than you are when you take warfarin.

Now, they'll come in here and tell you, "We told her

doctors that." They're never going to show you one piece of evidence that they told Betty that or that they told her family that. And that's the law in West Virginia. You have to tell the patient.

And you're going to hear from Rick and you're going to hear from Claudia. And you're going to hear if they had known even just one of these five things, they would never have asked for their mother to be switched from Coumadin to Pradaxa and we wouldn't be here today.

I'm going to touch on something with severe renal impairment. You're going to hear in this case about something called the company core data sheet. It's sort of like the MSDS sheet for drugs if you're familiar with the term MSDS.

This is where they keep all the information about their drug. This is an internal company document. We call it the CCDS because it's just a mouth full to say core company data sheet.

And what they have and what you'll see in their core company data sheet is exactly what I've just told you. There are no data to support the use of Pradaxa in patients with severe renal impairment. That means we haven't tested this drug in patients like Betty Knight. That's not a dispute. That's a fact.

Okay. And that brings us to May of 2013. What you're

going to hear is you're going to hear from Dr. Abdelgaber who is a primary care physician. He was Betty's primary care physician after Dr. MacFarland.

He will tell you that, and his records will show, and you'll hear this from Rick as well, on May 20th, 2013, Rick went to Betty's house. And when he got there, he discovered that she was bleeding. And her commode was actually filled with blood. And what he did was put her in his car and took her straight to Dr. Abdelgaber's office.

And when he got there, Dr. Abdelgaber took a look at her and he called an ambulance from his office to take her to the hospital. He had her admitted at St. Mary's and he treated her there. And he will tell you she had what is called a life-threatening bleed.

There are different degrees of bleeds. You can have a minor bleed. You can have what's called a major bleed. And then you can have what's called a life-threatening bleed. He will tell you, "This was a bleed that I thought was life-threatening." He'll say," That's why I put her in the hospital."

You'll hear that she had multiple blood transfusions while she was in the hospital and that she stayed in the in-patient section of the hospital for five days.

And then after that -- and this is the diagnosis -- excuse me -- the discharge summary. And you'll see why she

was there, severe gastrointestinal blood loss anemia.

She had a lower GI bleed caused by an AVM. What that is is it's a place in your, in your intestines. It doesn't normally bleed, but it did for Betty. And it bled because she was over-anticoagulated on Pradaxa. And he noted on there that she was on Pradaxa.

But when she -- and then you'll see that again she got four units of blood over that period of time. Her hemoglobin when she came into the hospital was 6. Normal is 12. They had to replace almost half of her blood because she had lost it from this GI bleed.

But when she got done with the in-patient stay, she didn't go home. They moved her right into the skilled nursing portion of St. Mary's Medical Center because she had such severe debility that was caused by the acute blood loss that she couldn't go home. So she stayed there another couple weeks. She was in the hospital for almost three weeks between the in-patient stay and the skilled nursing stay.

Betty was 84 years old. She wasn't in great shape to begin with. You put that kind of trauma on an 84-year-old and what you're going to hear from the witnesses in this case is that has a profound effect on their health. And that's exactly what happened to Betty.

After she got out of the hospital, or out of the

skilled nursing center, you're going to hear testimony that she never bounced back. She never felt like she was getting better. She kept coming back to the hospital. I expect the defense to say, "Well, that was for different stuff."

It was all related. It was all because she had been so severely debilitated and injured by this severe life-threatening gastrointestinal bleed that she couldn't recover. And she kept going back and back and back to the hospital.

And you'll hear from Dr. Abdelgaber himself. He'll say, "She just didn't bounce back. She didn't recover like I had hoped she would."

And then she passed away. On September 2nd she passed away. And I expect the defense will say, "Well, she didn't die from this. She didn't die from the bleed." And they're right. She died from cardiopulmonary arrest, the same thing anybody dies from. But that was caused or contributed to by a bleed that she had had, the severe gastrointestinal bleed that took such a toll on her body.

You're going to hear also in this case from Dr. Ashhab. He's a gastroenterologist. He's practiced in Charleston, West Virginia, since 2001. He treats gastrointestinal bleeds. That's what he does on a regular basis, daily basis.

He's board certified in internal medicine. He's board

certified in gastroenterology. He's going to tell you Betty was over-anticoagulated. She had too much Pradaxa in her system. Her blood was too thin. He's going to tell you that caused her to have the life-threatening bleed that she suffered.

And he's going to tell you that that bleed caused so much damage to her already frail body that she never recovered, and that that debility contributed to her death. That damage contributed to her death.

He's also going to tell you importantly she wouldn't have had that bleed had she been on Coumadin. He's going to tell you that.

Now, I want to tell you what I expect we're going to hear from the defense in this case.

Betty Knight was very sick. I assume that's going to be a central theme that you're going to hear from them once I sit down. That's right. She was very sick. She was the most vulnerable patient that this company could have sold the drug to.

She was so sick, the company excluded people like her from their drug trial, but they didn't exclude them from selling their drug to in the United States.

She was so sick that she never should have been on Pradaxa. That's a fact. She should have stayed on Coumadin because it's safer for her. And if she had done that, we

wouldn't be here today.

They're going to say, well, she had to be anticoagulated. She had atrial fibrillation. She has to take a blood thinner. I agree. She absolutely had to take a blood thinner.

She was successfully managed on Coumadin for six years. They're going to come in here and say she fluctuated wildly. They're going to show you a chart that says she was bouncing all over with her Coumadin levels.

Dr. MacFarland will testify. You will hear testimony. That's evidence in the case. And she will say unequivocally, "Every time Betty got out of range, out of whack, we were able to adjust it, got her right back in, and she never had a problem from warfarin." That's the testimony from her own doctor.

You're going to hear also none of Betty's doctors prompted this switch. That wasn't because -- none of them said, "Hey, you need to be on a different drug. You need to be on something besides Coumadin. This is not the drug for you." That didn't happen.

Boehringer played a TV commercial here in Huntington that was seen by Claudia and that prompted them to go in and ask your doctor about Pradaxa.

They're going to tell you the FDA approved Pradaxa, so it's fine. It's fine for us to sell to patients like Betty

because the FDA said it's okay.

Well, the FDA didn't approve Pradaxa 75-milligram dose based on any clinical trial. Computer simulations is what they did. That's what you're going to hear. They did computer simulations just to try to figure out: Does this drug work in a patient it's never been tried on before?

And we don't blame the FDA for doing that. Where the blame lays is that Boehringer didn't tell Betty or her family that fact so that they could make that decision. Do I want to be the guinea pig? Do I want to be the one they test this on? Or do I want to stay on the drug that works for me?

I expect you're going to hear this too. Hey, Pradaxa is better than warfarin. They're going to say it was found to be more effective than warfarin. That's right in the 150-milligram dose.

The 75-milligram dose has never, ever been compared head-to-head with warfarin. We have no idea if it's better at 75 milligrams than warfarin because they haven't run the test.

But they're going to come in here and tell you that. Look on the documents when they tell you that. You'll see 150-milligram. You're never going to see a 75-milligram reference.

And then they're going to tell you, "Hey, it wasn't

Pradaxa. It was Plavix that caused Betty's bleed." You'll recall we talked a lot about Plavix yesterday as well.

And what you're going to hear is that Betty did go on Plavix about a month before she had the bleed. And we don't dispute that it may have contributed to the bleed. But that's not our burden.

Our burden is to show you that Pradaxa was a substantial cause of her bleed. We don't have to show you that it was the only cause of her bleed.

And what Dr. Ashhab is going to explain to you is she was already so over-anticoagulated on Pradaxa, you can't put another medication on her. But because you can't test Pradaxa, because the drug company doesn't tell physicians, "Hey, here's how you find out if your patient's got too much in their system," her doctors didn't know that.

Even, even Boehringer's own expert witness they're going to bring to you, Dr. Crossley, he'll tell you Pradaxa contributed to the bleed. Yeah, it did. There's no question.

So then the question is: Why did Boehringer not tell Betty Knight the truth? This is the question that you're going to have to answer.

It's a huge market. The atrial fibrillation market was huge and untapped. Millions of people have AFib. Guess what. AFib doesn't come and go unless you have some sort of

procedure to get rid of it. It's a lifelong treatment. If you don't have cardioversion or ablation that works, you have to take a blood thinner for the rest of your life. How about that for a market?

And you'll see that the company knew that their potential to sell this drug, their potential to make billions from this drug -- and that's how drugs are sold, by the way.

Have you ever heard of the term "blockbuster drug"? That means you sold a billion dollars worth of it. Can you imagine that? A billion dollars worth of it. This is a blockbuster drug. And they knew the only way to get it there was to make sure doctors didn't think they had to measure patients' blood levels, even though the company knows they should and the company tells doctors in the rest of the world exactly how to do it.

I want to just end by showing you some photos so that you understand Betty Knight was a person. She lived here in Huntington. She, she grew up across the river in Ohio and then moved here, got married here, raised her family here.

That's her with Claude, Sr., and Rick whose real name is Claude, and Claudia.

When she got older, she was active. She traveled. She and Rick traveled together. They went to Greece together. She went to Daytona Beach.

She had grandsons, grandkids, many, many grandkids. That's her grandson's wedding.

This is her with her grandson's baby at the skilled nursing center after she had the bleed, one of the last pictures that we have of her.

That's her with Claudia and her daughters, her granddaughters, excuse me.

And this, that might be my favorite. This was from the world premiere of *We Are Marshall*. She was so excited about that movie. You'll hear from Rick. And she said, "This will never happen again in my lifetime." And she bought tickets for the three of them and they got all gussied up and they went together to see the world premier of that movie. And she was just so proud of her hometown.

And this is Betty's birthday. And that's Betty with Claudia and Rick and her grandson and her granddaughters, excuse me, her great-granddaughters.

I appreciate your time in listening to me this morning. I appreciate in advance the attention you're going to give to this case. And I thank you for your service. Thank you so much.

THE COURT: All right. The defense is going to present an opening statement. It's going to take them a couple of minutes to rearrange things. If you'd like to stand, stretch, move about, feel free to do so. If any of

you feel like you need a restroom break, go ahead.

(Pause in proceedings)

THE COURT: All right, we are ready now for the defense opening statement.

MS. JONES: Good morning, everyone.

It feels like it's been a little bit of a long time coming. My name is Phyllis Jones. I'm one of the lawyers for BI. I'm very pleased to have an opportunity to talk to all of you about the company's perspective on some of the evidence that you heard about from Mr. Childers. I'm going to talk to you about a good bit of evidence that you've not yet heard anything about in the case.

I am joined by John Lewis who will be sharing responsibility with me for examining the witnesses in the case.

You'll also see Gretchen Callas at counsel table with us. You'll probably see other folks coming and going just trying to help us stay organized and running efficiently. So forgive us in advance for any distractions in that regard.

Also here is Danielle Diviaio from Boehringer Ingelheim. She's one of the folks from the company and she will be here every day just like you all will be here every day because this is a really important case for the company and the same way that we understand it's a very important

case for the plaintiffs.

The thing that stuck with me after our long day together yesterday was how in a room full of strangers there were so many people who had been touched in some way by a stroke, either because they had a family member or some other loved one or friend who had somehow been affected by a stroke.

And the reason that Mrs. Knight took Pradaxa was because she was a patient who needed stroke protection.

Every doctor who comes into this courtroom, every doctor you hear testify on those television screens will tell you stroke can be a potentially devastating medical event, not just for the patient, but also for a patient's family. There will be no serious dispute about that in this case.

Mrs. Knight took Pradaxa for two years from October of 2011 until September of 2013 when she passed away, as you've heard, at the age of 84.

During those two years, Pradaxa worked for Mrs. Knight. It was an effective stroke prevention medicine for her.

Now, like -- I want to mention again those doctors you're going to see. Every doctor you see come into the courtroom, every doctor you see on those television screens are going to tell you that anticoagulant medicines like Pradaxa, not just Pradaxa, warfarin, some of the other

medicines you've heard about, Xarelto, Eliquis, every one of those medicines carries a risk of bleeding. You will hear that throughout the course of the case.

And you have heard that in May of 2013, Mrs. Knight had a gastrointestinal bleed. We will not dispute that. We will not dispute that that was a serious event that required medical attention.

But that was an event that was warned about. You will see those warnings. You have not had a chance to see them yet. You've only heard about what the company didn't say. I will show you those warnings during my presentation this morning.

It was warned about. It was managed by her doctor. They did a colonoscopy and they found the source of the bleed in her colon. And it was stopped within a day of her arriving at the hospital.

She spent two weeks at a skilled nursing facility after about a week in the hospital. And then she was discharged to go home.

And you have also heard that about three months later, Mrs. Knight passed away in September of 2013.

And, again, just thinking back on some of the conversations that we were having yesterday during jury selection, it is an incredibly difficult thing to lose a loved one. We will not dismiss that. We will not downplay

that. We will treat that with all the seriousness that it requires.

Looking at those pictures, I was thinking about my own family back in Oklahoma where I grew up. It's hard not to have a natural human emotion to that.

But what we will do is we will present you with evidence, evidence that responds to some of the very, very serious allegations you have heard regarding Boehringer Ingelheim, about the men and the women who work there. We will dispute those characterizations very strongly.

We will also present you with evidence on what is probably the central issue in the case, that -- an issue that runs through every single one of the claims that you heard the Judge describe earlier.

What happened with Mrs. Knight in September of 2013? What led to her passing? What caused her death? And although some of the evidence that we talk to you about will be complicated and technical, on that issue the evidence is straightforward.

Mrs. Knight passed away as a result of a heart attack. It was a heart attack caused by a years-long struggle with something known as coronary artery disease, something you haven't heard a thing about yet in regard to Mrs. Knight.

And you will hear that coronary artery disease is a very common disease, but it's a blockage of the vessels of

your heart. And over time what can happen is those vessels become blocked and it can cause a heart attack in patients who have that condition. That is the answer to that question; what happened with Mrs. Knight in September of 2013.

And you will not have to take my word on that question. You will not have to take the word of any lawyer in this room on that issue. And I would encourage you throughout the course of the case, as the Judge has instructed, to consider the evidence. Test anything that we have to say against the actual evidence in the case.

You were shown this document, the death certificate for Mrs. Knight from September of 2013. But you weren't told much about what it says.

At the top of it it says "cardiopulmonary arrest." And that's very common because that just means your heart has stopped. But what Dr. Abdelgaber said when he had to actually specify what led to Mrs. Knight's passing was, "I believe she had an acute myocardial infarction." I apologize. That's what doctors sometimes refer to as a heart attack, which is the doctor's way of saying it. And that was caused by coronary artery disease. That's what he said.

In real-time in the real world before any lawyers ever got involved, no mention of Pradaxa, no mention of a

gastrointestinal bleed that had happened three months prior.

He mentioned her long history of heart disease that had been so serious that her doctors had had to place multiple metal stents in the vessels of her heart to try to treat her. That, that is the evidence that answers that central question.

Now, I'm going to address the evidence as we see it in three categories.

First, I want to talk a little bit about Mrs. Knight's overall health and then talk about her heart conditions.

I'm going to talk about the warnings that BI gave not just to Mrs. Knight, although the company certainly gave warnings directly to Mrs. Knight, but also the warnings that the company gave to her doctors. You've not seen any of that in a case about failure to warn.

And, finally, I want to come back to that central question, that central issue of what happened with Mrs. Knight in September of 2013 and what does the evidence show on that central question.

I want to start with just Mrs. Knight's basic medical history. Mr. Childers previewed for you that I would get up and I would say Mrs. Knight was very sick.

The reason he knew that I would say that is because he has the same medical records that we have. That is the evidence in the case.

Mrs. Knight didn't just have a couple of conditions that her doctors were helping her manage. You will see throughout the course of the case that she had a number of serious chronic medical conditions that her doctors were helping her with: Serious kidney disease, hypertension, high cholesterol, diabetes. She had chronic weakness. She had issues with her heart which I'll talk about in more detail. She had smoked for many years. She stopped when she got a little older.

And I don't say any of that to criticize Mrs. Knight. She was doing the very best that she could. You'll see that in the medical records. Her doctors were doing the best that they could to help her. That's not a criticism.

But it's very hard to understand what happened with Mrs. Knight in September of 2013 without knowing what had been going on with her for many years prior to that time.

Now, you've heard about a three-week stay that Mrs. Knight had in 2013 when she had her GI bleed. The evidence will be that Mrs. Knight had actually, as a result of her medical condition, had to be in and out and in and out of the hospital on a number of occasions.

And this is just -- these are just snippets from records in the three years before Mrs. Knight ever took Pradaxa. She had a number of medical conditions that required her doctors to constantly be trying to help her

just get by day-to-day medically. That is the evidence on that issue.

Now, I want to talk a little bit about Mrs. Knight's heart condition. You've heard about atrial fibrillation. I don't think I can describe it any better than Mr. Childers did.

Essentially your blood can pool in a chamber of your heart because you have a heart rhythm problem. And that clot that can form there can travel to your brain and it causes a clot to become lodged in the vessel. And that can cause what's known as a stroke.

Depending on how large the clot is, depending on where that clot actually lands, it can cause serious problems with just basic function because our brain controls all the things we're able to do every day.

The other condition that Mrs. Knight had that you've not heard anything about but is really important in this case in part because, as I mentioned, it's featured on her death certificate that her primary care doctor filled out is a condition known as coronary artery disease.

Now, we've put together this board. Can you folks see this okay? We've put together this board just to show the basic anatomy of the outside of the heart.

These red vessels are coronary arteries that carry blood and oxygen and nutrients to the muscles of the heart

so it's able to pump the way it's supposed to. When we were all born, our coronary arteries were smooth and clear and everything traveled through them without any problem.

What can happen over the course of a life is that you can start to develop plaque in the coronary artery. And that can become progressively developed such that that vessel over time can close more and more.

Now, in the worst case scenario, what can happen with that plaque is there can be a crack in it. And when the body's natural clotting system -- and our body is always looking for ways to protect us from things -- the body's natural clotting system sends a blood clot to that location and it can close the vessel off almost entirely or completely.

And that's what's known as a heart attack because blood and oxygen can't travel to the heart muscle. And, so, heart muscle actually dies when people have heart attacks.

Now, even when patients don't have a heart attack, the worst case scenario for a patient with coronary artery disease, they can have other symptoms. And you will see that in Mrs. Knight's records.

She had something called cardiomyopathy, which is just a disease of the heart muscle that can be caused by it being deprived of oxygen.

She had congestive heart failure where her heart had a

harder time beating the way that it was supposed to. She had chest pain, which is a very common symptom for patients who have a condition where their -- the muscles of their heart just aren't getting enough oxygen and enough blood and nutrients.

Now, Mrs. Knight's doctors -- you will see this in the records over the course of her life, including before she ever took Pradaxa. Her doctors were working with her very hard to manage two conditions; on the one hand, her coronary artery disease because they were trying to protect her from having a heart attack.

On the other hand, they were also working with her to manage her atrial fibrillation to try to protect her from a stroke.

Now, these are two different conditions. They're treated differently. When patients have coronary artery disease and it proceeds and it's serious enough, what doctors will do is they will place metal stents in the vessels of the heart.

And that's actually what happened with Mrs. Knight. Back in 2008 before she ever took any Pradaxa, her doctor did a procedure to actually look in the vessels of the heart and figure out how blocked were they.

And what they found when they did that procedure was that she had a 90 percent blockage in a vessel on the left

side of her heart. They found that she had a 30 percent blockage on a vessel also on the left side of her heart. And then they found that she had a 70 to 80 percent blockage in a third part of the vessels on the left side of her heart.

On the right side of her heart Mrs. Knight's doctors found a 50 percent blockage on a vessel running down along the bottom. And they found what they called mild diffuse disease on the right-hand side. That's just another way of saying they found blockage all over.

Now, we will call an expert cardiologist named George Crossley from Vanderbilt University. And he'll come in and talk to you about all of the mechanics of this. But one of the things that he'll tell you is that any one of those blockages could cause a heart attack because any part of that plaque could crack and a blood vessel could form -- that a blood clot could form that would actually keep oxygen and blood from traveling to the heart muscles.

So Mrs. Knight's doctors in 2008 and then in 2009 placed two stents in her heart, one in the most serious blockage of 90 percent and another in that area where they found a blockage of 70 to 80 percent to try to keep those vessels open to try to prevent some of the conditions that I've talked about that go along with having coronary artery disease.

Now, Pradaxa and medicines like Pradaxa, blood thinners generally, treat atrial fibrillation. And, so, Pradaxa doesn't have anything to do with Mrs. Knight's coronary artery disease. That was really something doctors were giving her to try to prevent her from having a stroke.

And one of the reasons that doctors are so concerned about treating patients who have atrial fibrillation is because what it can mean for a patient's risk of having a stroke.

Patients who have atrial fibrillation have a five-times increased risk of stroke. And I want to be fair in the way that I describe what this means because every patient is different.

There are patients who have a stroke, and because the clot is small or it doesn't go to a critical part of the brain, they are able to fully recover and walk out of the hospital under their own power. And that is absolutely what doctors hope for and what family members hope for if you have a loved one who has a stroke.

But for many patients, a stroke can be life-changing. Strokes can be fatal. Every four minutes in the United States a patient dies from a stroke. 100,000 Americans die from stroke every single year.

And for patients who survive their stroke, their lives can be changed in ways that I think it's hard for us to even

imagine because a stroke can rob you of the ability to do all the things that we do as a matter of routine and don't think about.

If you just think about the things you had to do to get here this morning, getting out of bed on your own, cleaning yourself on your own, going to the bathroom, saying "good morning" and "I love you" to your loved ones. A stroke can rob a person of living daily lives and can affect all the people in that patient's life. That's why doctors care so much about treating patients with AFib.

Now, you've already heard about anticoagulants. I will tell you -- I don't think this will be a disputed point in the case -- every prescription medicine has benefits, things that are good about the medicine, and risks or potential side effects.

And prescription anticoagulants are no different. Prescription anticoagulants reduce the risk of a patient having a stroke. That's why doctors give them to patients. They also increase a patient's risk of having a bleed. Every single oral anticoagulant increases a risk of bleeding.

Now, when doctors are making a decision about whether or not you want to expose a patient to the risk of bleeding to try to protect them from stroke, one of the things that they have to do is look at the patient and evaluate what is

this patient's stroke risk.

And Dr. Crossley will explain to you all that they often use a metric. They -- where they add up different factors and figure out what does that mean for the likelihood that this patient might have a stroke.

And in Ms. Knight's case, you will hear from Dr. Crossley. She had the highest conceivable stroke risk that would have been possible for someone like her. She was over the age of 75. She was a woman. It turns out women have a higher risk of stroke than men do. She had had a stroke before. You will hear about that in the evidence. And when you have a stroke, your risk of having another one goes up automatically.

And then some of those same chronic conditions that I mentioned earlier also are calculated in a patient's stroke risk; hypertension, vessel disease where your vessels are somehow clogged up, diabetes, congestive heart failure. All of that together meant that Mrs. Knight's risk of stroke was incredibly high.

And all of her doctors, Dr. MacFarland, Dr. Abdelgaber, Dr. Gunnalaugsson, they will all tell you this was a patient who had to be treated with an anticoagulant. Again, Mr. Childers knew I would say that because that is the testimony of each and every one of the doctors who treated her. And it will be the testimony of Dr. Crossley who has spent his

career treating patients like Mrs. Knight who have atrial fibrillation.

Now, when Mrs. Knight was first diagnosed with atrial fibrillation, the only option for patients for stroke protection was warfarin or Coumadin, a medicine you've now heard discussed at great length. And it sounds like folks have a lot of experience with it.

If you presented to a doctor and were diagnosed with atrial fibrillation, that doctor could give you one medicine and only one. That was warfarin. For 50 years it was the only option available.

And this is not a case about whether or not warfarin is sometimes a good medicine. There are many patients who are on warfarin and do fine. This is a case about what was warfarin like for Mrs. Knight.

Now, I want to spend some time talking about that.

One of the things that's unusual about warfarin that makes it different from a lot of prescription patients -- prescription medicines is that patients have to be kept within a very narrow range to use it safely and effectively. They have to be kept between a two or a three on what's known as INR, which is a short way of saying international normalized ratio.

Now, when a patient is within that range, a patient can have a stroke, a patient can have a bleed. It does not

protect you from those things. But over the years, doctors and scientists have determined that to use the medicine safely and get the benefit that you want, that's where patients should be.

Now, if you're not in that range, your risk for both of those things, a stroke or a bleed, increase. Your risk of having a stroke increases by 400 percent if you are below a two in terms of your INR. Your risk of having a bleed goes up by 200 percent if you're over a three in terms of your INR.

And some patients don't have a problem staying in that range of two to three for whatever reason. Doctors don't always know why some patients do fine and some patients don't.

What we do know is that in Mrs. Knight's case, she had challenges with that. You can see here -- Mr. Childers previewed this for you all -- this just is a graphic that reflects how Mrs. Knight did when she was on warfarin.

There were periods where she was within range. There's no question about that. But there were also periods where she was below a two and her stroke risk would have been higher. And there were periods where she was well above three where her bleeding risk would have been dramatically higher.

And Dr. MacFarland when she was deposed in this case

was asked, "What do you think about how Mrs. Knight did in terms of her INR control when she was on warfarin?" This was her sworn testimony; that her INR was pretty variable, not always therapeutic, wildly variable.

That was Mrs. Knight's experience on the medicine. And that's the testimony of one of the doctors who treated her when she was on warfarin.

Now, there are a lot of reasons that patients sometimes have challenges with warfarin. One you've heard mentioned, there are food interactions with warfarin. These are just some examples of some of the foods that we interact with all the time, onions, garlic, celery, broccoli, that depending on the patient can affect your ability to stay within that range.

We also know that warfarin has a number of drug interactions. Warfarin as a medicine is probably at the very, very top of the list in terms of all of the medicines that it interacts with and the way that that can complicate a patient's INR control.

You'll hear that some of those medicines were medicines that Mrs. Knight had to take for other conditions that she was managing.

Now, I want to focus in a little bit on the evidence of what all this meant for Mrs. Knight's time on warfarin because you have been told that she did just fine on the

medicine and it was just that her numbers were zigging and zagging. But as a practical matter, what it meant is that it was very challenging for her doctors at times to keep her consistently on the medicine.

You'll also hear that when doctors prescribe anticoagulants or blood thinners for AFib patients, they want them to be able to stay on the medicine because every day, every week, every month that you're off the medicine, you're exposed to a risk of having a stroke.

This is just a six-month window that I'm going to walk through of Mrs. Knight's time on warfarin starting in August of 2008. And this is hard to read, so I'm going to read it for you all. This is taken from a record from that time.

She reported that she was off of Coumadin. She didn't want to come to the office to get blood work checked as frequently as you need to with Coumadin. She declined to be on Coumadin.

Now, that's not uncommon. That was not a failing on Mrs. Knight's part. A lot of patients decide that they just can't do the blood monitoring for whatever reason. And that was her feeling in August of 2008.

Fast forward about a month and a half. Mrs. Knight went back to her doctor. And her doctor documented in her records Mrs. Knight absolutely needs to get back on her Coumadin because her risk of having another stroke with her

chronic atrial fibrillation is high.

Now, in September of 2008 there was no other option for Mrs. Knight. There was just that one medicine that she already said, "I really don't want to take that." But because her risk of stroke was so high, her doctors put her back on Coumadin.

Fast forward a little bit more. You'll see there's a record from November of 2008 where it was reported that she had been on Coumadin for atrial fibrillation, but this was stopped because of her chronic bleed.

Now, you've been told that Mrs. Knight never had a bleed while she was on warfarin. And, again, I'm just going to ask you to judge what we've said against the actual records in the case.

This is just one example of a record that confirms that Mrs. Knight's doctors believed at the time in real-time that she was having somekind of bleed that required her to come off of her warfarin treatment.

Fast forward to the following year, February of 2009. Mrs. Knight presented to the hospital complaining of pain in her right arm and her fingers were becoming discolored. And when her doctors did a CT to figure out what was going on, it was the very thing that doctors hear so much with patients on atrial fibrillation. She had thrown a clot while she was off of warfarin that just so happened to go to

her arm. Thankfully it didn't travel to one of her critical organs. It didn't travel to her brain. But her doctors made the judgment that she needed to be back on warfarin.

You'll see the last record reflected here. She had not been on Coumadin because of a GI bleed. There's another reference to her doctor's belief that she had a bleed.

She had an embolus down her right arm which just means she had a clot. An embolus is just a clot. And it had landed in her right arm. And, so, they restarted her on warfarin.

Now, this was not the entirety of Mrs. Knight's time on warfarin. There were times where she did fine on it. But for a patient who needed to be on an anticoagulant every day and every week of every month, this was a really dangerous situation for her to have to come on and come off because of struggles that she was having on the medicine.

Those struggles continued. And although what you've been told is that the only reason that she moved to Pradaxa is because someone in her family saw a television ad, the evidence actually is that those concerned about her INR control continued right up until the time that she was moved to Pradaxa. This is just an image of the week before Mrs. Knight moved from warfarin to Pradaxa in October of 2011.

On October the 10th Mrs. Knight had her INR checked and it was at an eight which is well above that three that she's

supposed to be at. Her bleeding risk was very high, so high that her doctor said, "You need to get her to the ER. This is very serious."

On October the 12th, two days later, her INR had dropped, but not nearly enough to get her back into a safe range, what was viewed as a safe range.

A day later for some reason her INR went back up in the wrong direction. It went up to 6.3. And then yet another day later it dropped down, but not far enough to get her within range.

And then for some reason, by October the 17th her INR had dropped past the therapeutic range, past that range that her doctors were aiming for and below the range so that her stroke risk was increased.

Those were the circumstances. That was what was going on when the decision was made to move her from warfarin to Pradaxa.

You will see in the evidence that there was a specific request by her son to consider replacing Coumadin with a new drug. And you will also see the documentation that Dr. MacFarland had to fill out because if you all have any experience with getting your prescriptions covered by insurance companies, you sometimes have to justify why you might be moving from one type of medicine to a different medicine.

And in this instance, Dr. MacFarland had to explain why are you taking someone off of something that's already been good for her, a question that, frankly, will be posed in this case, and moving her to something else.

And what she said was the patient is sporadic and supratherapeutic, which really just means she's all over the place in terms of her INR and has been since 2008 until the present. And then she indicated on that form that she was being moved to the 75-milligram dose of Pradaxa.

Those were the circumstances. Those were the events leading to Mrs. Knight's change from warfarin to Pradaxa.

And you will hear from the doctors in the case that that was a reasonable decision on the part of Dr. MacFarland. You'll hear that from the doctors who cared for her. You'll also hear that from Dr. Crossley who was the only expert cardiologist who actually looked at her medical records and had a chance to evaluate that.

Now, Mrs. Knight's experience specifically and the experience of many patients who had challenges with warfarin, that's really what motivated the interest in developing not just Pradaxa, but other new medicines to treat patients with atrial fibrillation; this feeling among doctors that there needed to be an alternative to warfarin because for some patients, not all, but for some patients, warfarin just wasn't a manageable option. That's what led

the company to look into developing something.

And Pradaxa was developed in the way that many prescription medicines are developed, over years and years of study starting with just lab, test tube research, and then carrying on for many years of study in human volunteers who participated in all kinds of studies about the medicine.

Now, the biggest clinical trial related to Pradaxa was something known as the RE-LY study, RE-LY. You may hear that throughout the course of the trial.

And in that study, the company studied two doses of Pradaxa, the 150 and the 110. And they put patients on those medicines without blood monitoring and checked how they did against patients who were on warfarin with blood monitoring. And after they submitted the results of that data, the medicine was approved in the United States.

Now, just to go through the results of that study for the 150-milligram dose against warfarin, again Pradaxa patients without blood monitoring, warfarin patients with blood monitoring, Pradaxa 150 did better on various, what doctors call endpoints, but basically it's just how folks do on certain medical events.

There were fewer strokes on Pradaxa, fewer life-threatening bleeds, fewer brain bleeds, what's known as an intracranial hemorrhage.

The one place where the study showed that Pradaxa

didn't do as well as warfarin was that patients who are on Pradaxa had more gastrointestinal bleeds, bleeds in the GI system.

Now, the way this process works in the United States is that the company takes all the data it's gathered and submits it to the U.S. Food and Drug Administration, the public health agency responsible in this country for evaluating new prescription medicines.

And that's what Boehringer did. They said, "We think based on this data that we should have two doses approved for AFib patients in the United States, 150 milligrams and 110 milligrams."

And, so, they submitted what you will hear described as a new drug application for those two doses of Pradaxa.

Now, the FDA has the ability to look at all the data that the company submits. You will hear that the FDA did just that in the case of Pradaxa.

And the FDA decided, "We think the 150 should be approved but we don't think there should be a 110 dose." And there won't be any fussing between the parties about that.

What the FDA went on to say was, "We think there should be a half dose of Pradaxa." And the reason they wanted to do that is because there was a population of patients like Mrs. Knight who have severe kidney problems who the FDA said

needed an option, needed an alternative to warfarin.

And, so, even though the 75-milligram dose wasn't tested in RE-LY, the FDA did its own analysis and determined based on the data that it had that the 75-milligram dose would be an appropriate option for patients with severe renal impairment. That was their judgment based on looking at all the data that was available to it.

And, so, what happened in 2010 is the FDA actually published a memo describing its thinking. And you will see this memo in the course of the case.

And what they said was the division -- that's just a reference to the team of people who looked at the application -- the division concluded that the best tact, which just means the best approach, is to assure that the population with severe renal dysfunction -- that just means people who have bad kidneys -- not on dialysis would have access to dabigatran, which is another name for Pradaxa.

The FDA viewed it as so important that patients like Mrs. Knight have access to an alternative to warfarin that they made a judgment based on the data that a half dose should be made available. That will be the evidence on that issue.

And, so, the FDA directed the company to create a half dose. The sponsor should manufacture a lower strength of 75-milligram. This strength will allow for dose adjustments

in patients like Mrs. Knight who have severe renal impairment.

And that's what the company did. As you've now heard, there are two doses of Pradaxa. There's a 150-milligram dose for patients who have kidney function above a certain level. And for patients who have kidney function below that level, they take a half dose of the medicine. And that was based on the FDA's conclusion that that was the right way to provide an option for these patients.

I want to turn now to talking about the warning in the case. You have been told this is a failure to warn case. You have been told that the warnings are where the rubber hits the road.

But you were not shown a single warning that the company actually provided to Mrs. Knight or that the company provided to her doctors. And, so, I want to spend a little bit of time showing you parts of those warnings. You will see all of them in the course of the trial.

Now, the other part of the medicine approval process in the United States is that the company makes a proposal for labeling.

Part of that labeling is something known as a Medication Guide. A Medication Guide is something that by law every time a patient picks up a prescription for Pradaxa, the Medication Guide has to be handed out every

single time.

So every time Mrs. Knight's prescription was picked up for her Pradaxa over her two years using the medicine, she should have gotten a copy of the Medication Guide.

And you will hear that the Medication Guide is written for patients. It's written in language that's intended for patients. So there's a lot of technical information that's not included in that document necessarily.

But if a patient went to a pharmacy with a prescription for Pradaxa to fill it and the only question that the patient had was what is the most important information that I need to know about this medicine, this is what the patient would be told. Pradaxa can cause bleeding which can be serious and sometimes lead to death; a very direct, a very serious warning, a warning that applies to everyone, men and women, no matter what medicine you're on, no matter what other conditions you have. That warning applies to you.

And that's not unique to Pradaxa. If you looked at all the labels for all the oral anticoagulants, they all have the same type of warning in the label.

Now, the Medication Guide also flags for patients: Here are some conditions or patient factors that might increase your risk of bleeding. If you're older, if you're over the age of 75 you have a higher risk of bleeding.

If, like Mrs. Knight, you have kidney problems, you

could have a greater risk of bleeding.

If you take other medicines that increase the risk of bleeding like aspirin, like Plavix, you might have an increased risk of bleeding. And that will be important when we move towards talking about what happened with Mrs. Knight in 2013.

That information and more is provided to patients in the Medication Guide. And the Medication Guide tells patients because Pradaxa is a prescription medicine, talk to your doctor. Tell them about the issues you have. Tell them about every medicine that you're taking. That's all communicated in this document.

The other thing that the Medication Guide does is it tells patients: Here's what to look out for while you're taking the medicine. Some of it is obvious. If you have a bleed that you can't control that you can see on your hand, for example, that you're just not able to get the bleeding to stop, you should talk to your doctor about that, but also other things.

Now, these might be signs of bleeding. They might be something else. But the Medication Guide says be sure that you get in touch with your doctor about these issues if you see them develop while you're taking the medicine.

The last point that I want to touch on on the Medication Guide is that it is not the only resource for

patients. You will hear, I believe, in the evidence that Mrs. Knight relied to some extent on her doctors in making decisions about what medicines she would or would not take to help treat her various conditions.

And the Medication Guide is very clear. This is not your only tool. It does not take the place of talking with your doctor. And if you want more information, if you have questions, please be sure to talk to your doctor.

And the company encourages and supports that decision by also making a label available to doctors.

Now, the label for doctors is a different document. It's longer. It's more detailed. It's more technical. It has statistics in it that you might not find in a patient document.

But it starts with that very same, very direct, very serious warning. Pradaxa can cause serious and sometimes fatal bleeding. This is literally a medicine that can cause bleeding that is so serious that it could cause you to pass away. That has been in the label for Pradaxa since the day that the medicine was approved eight years ago.

It goes on to talk to doctors about certain risks of high-risk patients, patients who for whatever reason might have an increased risk of bleeding. Older patients have an increased risk of bleeding. Patients like Mrs. Knight who had kidney problems have a higher risk of bleeding.

Patients who take certain medicines like NSAIDs, like aspirin, like the anti-platelet medicines you heard talked about earlier, all of those things increase a patient's risk. And the company very directly warns about that.

Now, you saw a list of various items that you've been told the company didn't tell Mrs. Knight about. That information is provided to doctors, including on the very specific risks of GI bleeding with Pradaxa. In the RE-LY study the company saw that there was an increased rate of GI bleeding versus patients who were on warfarin.

And, so, the company's obligation is to warn the patient. You have heard that. That is the law of West Virginia. But part of the way the company does that is by equipping doctors with other information that can be communicated to their patients.

Now, the other thing that you will hear about Mrs. Knight's care while she was on anticoagulant medicine is that for various reasons, she sometimes had home health support, people who come into the house that make sure you're eating. They help you with your medicines. They help pick up the house sometimes. And those folks were also reinforcing all of these warnings that you've now seen in the labeling for Pradaxa. And that went back all the way to when Mrs. Knight was still on warfarin.

This is also hard to read, so I'll read a couple of

them. Educated patient on Coumadin therapy to report any signs or symptoms of abnormal bleeding such as bruising, blood or black, tarry stools.

And those types of, those types of recommendations continued when Mrs. Knight was moved to Pradaxa. Patient and CG, which we think is a reference to care giver, instructed on high-risk med Pradaxa for treatment of anticoagulation.

And then the same types of suggestions. Keep an eye out for the signs and the symptoms of bleeding. There will be no question in this case that there was information provided at various points during Mrs. Knight's care about the risk of bleeding with anticoagulant therapy.

You will also see in these same home health records various references to Mrs. Knight, and in some cases her care givers, her children, verbalizing understanding, verbally stating, "We understand the education that's being provided."

And you will hear the testimony of Mrs. Knight's doctors, all of whom will tell you, "We knew there was a risk of bleeding with anticoagulant therapy. That's a commonly understood risk with blood thinner medications, and we understood it with respect to Mrs. Knight."

Now, in the face of all of those warnings which you have now seen, what you've been told is that the company

somehow didn't want to tell doctors about the need to monitor patients on Pradaxa. And this is another place where I would ask you to compare what you hear from us lawyers against the actual evidence in the case.

On that particular issue you only need to look as far as the label for Pradaxa which very clearly tells doctors to monitor, but tells doctors to monitor the feature of the patient that's most likely to influence how much medicine the patient has in his or her system. And that's kidney function.

This is a section from the Pradaxa label written for doctors that says exactly that. Assess renal function prior to the initiation of treatment with Pradaxa. That means check the patient to figure out which of those two doses the patient should be on.

And then you keep assessing renal functions as clinically indicated, which means whatever is going on with the patient medically, you might need to check kidney function more or less.

And you heard from Mr. Childers it's a nice thing when patients have communications with their doctors and their doctors are checking in with them regularly. That was the case with Mrs. Knight when she was on Pradaxa because her doctors were looking at her kidney function.

So doctors are told periodically assess, which just

means keep checking as necessary. You can adjust therapy if it becomes appropriate.

And then it goes on to say discontinue Pradaxa in patients who develop acute renal failure while on Pradaxa and consider alternative anticoagulant therapy.

That means you may have to move the patient from Pradaxa to something else if it turns out based on monitoring kidney function that that patient is no longer a good patient for Pradaxa treatment.

And you'll see in the evidence that Mrs. Knight's doctors did that. They checked her kidney function before she ever started the medicine. And then on various occasions while she was being treated with Pradaxa, they kept checking her kidney function to make sure that there was nothing going on that would affect in a problematic way her exposure to the medicine.

And that's a common sense thing. If kidney function, as you've heard, is the thing that determines how much of the medicine you have in your system, what's the thing you'd want your doctor to be checking? Your kidney function. And that's what the company has always encouraged doctors to do.

Now, what you've heard in addition to some of the challenges to the labeling is that the company should have done more. And the question was whether or not when you have a patient on Pradaxa who's already getting her kidney

function monitored on a regular basis by a doctor, just the way the label says you have to, do you also need to subject that patient to blood monitoring like patients have on warfarin to make the medicine better or safer?

And that was not an idea that originated in this litigation. The company specifically looked at whether or not that would be a good thing to do. That's not something we will walk away from. It's not something we're going to dispute.

The company collected data on blood levels in the RE-LY study from 9,000 patients. All that data -- you will hear this -- was submitted to the FDA. And the FDA had the opportunity to look at that data.

You'll see curves I think at various points in the trial where the FDA was looking to see if your blood levels are higher, what does that mean for your bleed risk? If they're lower, what does that mean for your bleed risk? And the same thing for stroke risk. The company looked at it. They gave the data to the FDA. The FDA looked at it.

Now, the company had a real conversation about this. You will see various emails from folks at the company talking about whether this is a good idea; is there a magic range; is there a magic number; is there a spot where patients can be most safely treated with the medicine. That was hotly debated.

And I don't want it to be any surprise to you when you see people at the company going back and forth over whether it would be a good idea. You will see that because it was a real conversation among scientists and doctors who were studying the medicine.

But ultimately what the company concluded after looking at the data, some of the curves that they developed as a result of that analysis, was that there was no single plasma concentration range that provides optimal benefit risks for all patients.

That's a fancy way of saying there's no magic number. There's no magic range. If you've got patients whose kidneys are being monitored, you don't also have to subject those patients to blood monitoring. They can be safely monitored through kidney function.

And that's what they reported in the article that was published. Renal function was the predominant patient characteristic that determined plasma concentration for Pradaxa patients.

And you will have to consider in this case for Mrs. Knight, a patient who you've now seen had her kidney function regularly monitored while she was on the medicine, whether having blood monitoring on top of that would have somehow changed what ultimately happened with her.

And that's, that's the last topic that I want to

address as I come to my conclusion. And that's this issue of what happened with Mrs. Knight in the spring and the summer and the fall of 2013, that central question that I mentioned to you earlier.

Mrs. Knight was on Pradaxa for 19 months with no issues. She did well on the medicine. She had no stroke. It was an effective, good medicine for her. It worked for her.

At the same time, her other medical conditions were becoming more serious. And you can see listed here some of the symptoms reported or documented by her doctors in her medical record; a suspected heart attack in October of 2011, high blood pressure, cardiomyopathy, which is that disease of the heart muscle, chest pain, shortness of breath.

Those are all conditions and symptoms that go back to this image we were looking at earlier, the issues that patients sometimes have when they have coronary artery disease that is a progressive condition.

In April of 2013 Mrs. Knight had a heart attack. And her doctors did another procedure for her where they actually looked in her vessels again, now three years later, excuse me, now five years later. And they found what they described in the record as, quote/unquote, new stenoses. And that's just a way of saying we found new places in her heart that seem to be blocked.

And when they did that analysis based on that procedure, they actually found an additional 90 percent blockage over here on the left side of her heart. And as a result, they placed two additional stents in addition to the two that she already had. She then had four metal stents that had to be placed in her heart.

And as a result of the placement of those stents, her doctors had to put her on an additional medicine that you've now heard about known as Plavix. Plavix is an anti-platelet agent. Plavix is a medicine that prevents the platelets in our blood from sticking together so a clot won't form.

So Mrs. Knight was on Pradaxa because she had AFib and she needed stroke protection. Her doctors had her on a dose of aspirin just to manage her general cardiac condition. And then they added to that Plavix.

Now, Dr. Crossley will testify that cardiologists are well aware that that combination of medicines, all of which have their own risk of bleeding, increase a patient's risk of bleeding. That will not be a disputed issue in the case.

And that's warned about, as you'll recall, in the Medication Guide for Pradaxa. You may have a higher risk of bleeding if you take Pradaxa and aspirin or aspirin-containing products and you take something known as Plavix or Clopidagrel which is just another name for Plavix.

It's also warned about, as I mentioned, in the labeling

for Pradaxa. There's that reference in the label, which I know is a little hard to see, that one of the risk factors for bleeding includes a concomitant, or a same-time-as, use of other drugs that increase the risk of bleeding, including anti-platelet medicines like Plavix.

So this is a well understood risk of patients who have a stent placed and have to have Plavix in addition to other medicines that they might be taking for other conditions.

Now, the thing that happened with Mrs. Knight in May of 2013 was not that something changed with her Pradaxa. It was that because of her stent, she had to have Plavix added to her medicine list.

And she was on Plavix for a little less than a month and she had a bleed. That was the sequence of events.

Now, I want to be very clear about something. Pradaxa is an anticoagulant. And if you have a bleed that's going on and you're on an anticoagulant, there's no question that that could have a role in that bleed.

But the important thing to know there is that's the case with any anticoagulant, with warfarin, with Xarelto, with Eliquis. That is the way that those medicines work. There will not be evidence that warfarin, had it been the anticoagulant that she was on, would have somehow changed her risk.

Mrs. Knight had her bleed on May the 20th, as you've

heard. What you did not hear about her bleed was that it was warned about. You've now seen that warning in the labeling for Pradaxa was given to doctors. It's also, of course, that broad warning about the risk of serious and fatal bleeding.

It was caused by something known as an arterial venous malformation. I think Mr. Childers mentioned this, an AVM. They are very common in older people. They're basically a vessel that's formed in the colon. And they can bleed without an anticoagulant. They can bleed with an anticoagulant. And they can bleed with any anticoagulant. It doesn't make a difference what the medicine is.

The other thing to know about that bleed it that it was stopped. It was fully stopped in May of 2013. They did a colonoscopy. The gastroenterologist who treated her saw the bleed in her colon. He placed clips there. And she was able to be returned back to her hospital room. And then eventually she was discharged at the beginning of June of 2013.

Now, when Mrs. Knight was discharged, she was put back on Pradaxa. And I want to talk a little bit about that decision by her doctors. They stopped her Plavix. And you'll see this in the records. He didn't want her to be back on Plavix due to the history of gastrointestinal bleeding.

But the doctors went on to conclude that, "I do not think that the Pradaxa could be held in the long-term given her multiple issues with blood clots."

In other words, this is a patient who has to have anticoagulant therapy and we still think that Pradaxa is the appropriate medicine for her.

And until she passed away in September of 2013, Mrs. Knight's doctors kept her on Pradaxa because they thought it was important for her to continue to receive effective stroke prevention, which is what she got when she was on Pradaxa. It was a good medicine for her.

Now, you have been told that after Mrs. Knight was discharged in June of 2013, she didn't bounce back. And you didn't get a lot of detail about what happened between June and September of 2013. You might have thought there must have been something else going on here. There was. And you will see the records on what happened during that three-month period.

In each of those records you will see references to the types of symptoms that were common for Mrs. Knight because of her coronary artery disease. And you'll see references in some of the records where the doctors had a chance to say: Was this something the patient has experienced previously?

And at various points the doctor said, "Yeah, this was

something that the patient has been dealing with for a long time."

She presented in July with chest pain, similar symptoms previously, yes, several times.

She presented in August with a suspected heart attack, similar symptoms previously. Yes, patient has a history of chest pain.

And then in September of 2013 Mrs. Knight had a heart attack. And, again, when her doctors had to fill in that spot where it says has this patient had these types of symptoms before, they didn't talk about Pradaxa. They didn't talk about a GI bleed that had happened months before. They said these are the same types of heart challenges that she has had for a long time.

And on September the 2nd of 2013 Mrs. Knight passed away.

Now, you've been given a very narrow impression of Mrs. Knight's medical history in terms of trying to explain what happened with her in the fall of 2013. But when you look at that evidence in light of all that she had been dealing with, not as a result of Pradaxa, but as a result of long-standing heart disease that her doctors had been working with her to try to treat and try to manage, you see that this was a progressive disease process for her, that her doctors were trying to do the best that they could but

you see the same types of symptoms going on over the course of many years, including years before she ever took Pradaxa:

Coronary artery disease; chest pain; cardiomyopathy, that disease of the heart muscle that results from not having enough oxygen and nutrients and blood; congestive heart failure, just problems of the heart pumping the way it's supposed to; stenosis, which is that blockage of the vessel that you've now heard about; the need for stents. By this time, she had had to have four stents placed in her heart.

And then ultimately at various points in time heart attack symptoms, places where her doctors thought she had had a heart attack, and then a heart attack that ultimately led to her passing in September of 2013.

And I will end where I began with the real-time, real world account of her doctor who had the very difficult task of documenting, taking pen, putting it to paper and saying, "This is what I think happened with this patient."

He mentioned cardiopulmonary arrest. And he reported that she had had -- the thing that caused her heart to stop was that she had had a heart attack which you've now heard described as a myocardial infarction, and that the cause of that heart attack had nothing to do with Pradaxa. It was because she had had on-going heart disease, severe heart disease for many years described on the death certificate as

atherosclerotic coronary artery disease caused by hyperlipidemia, which is just a long way of saying high cholesterol.

Now, there's another section on the death certificate down at the very bottom. And this is very tough to read so I'll read it for you all.

It says, "Other significant conditions contributing to death but not resulting in the underlying cause." So this is another section where a doctor if he or she feels there was something else going on with this patient that I think was also adding to what happened with her. The doctor can list that.

Dr. Abdelgaber, given that opportunity, didn't mention Pradaxa, did not mention a gastrointestinal bleed. He mentioned the same type of chronic conditions that Mrs. Knight's doctors had been working with her to try to treat for years, congestive heart failure, hypertension, high blood pressure, chronic kidney disease, the reason that she been put on that half dose of Pradaxa, and dementia, no mention of a GI bleed that had happened months earlier.

That is the evidence created in real-time reflecting the judgment of her doctor on what happened with her in September of 2013.

I am very grateful to all of you for your patience. It was a long day yesterday. And we are very grateful for the

attention and the patience you will give us over the course of the next three weeks or so.

We are going to do our best not to waste your time. We will have an opportunity to cross-examine the plaintiffs' witnesses and we will do that.

In our part of the case we are going to present you with medical doctors who when they are not in the courtroom they are back at their respective employers treating patients just like Mrs. Knight.

And at the end of the case, we are going to ask you to enter a verdict for BI because that is what the evidence supports.

Thank you all so much for your attention.

THE COURT: All right. You've heard the opening statements. We're going to take a lunch break now, but let me go over a couple matters with you.

First, I want to tell you generally what schedule we'll follow for this trial.

Every day we'll start at 9:00.

Does anyone have more than a half an hour or 45-minute drive to get here in the morning? How long? How long? Hour? So we've got three or four of you have an hour. Well, is 9:00 too early? Would it be better to come a little bit later?

All right, we'll try it at 9:00. If it starts to be a

problem, let me know.

Generally we'll start around 9:00. We'll take a mid-morning break at 10:30 or 11:00 at a convenient point. I'll let you go back into the jury room.

We'll take a lunch break around noon. Again, I'll try to pick a convenient point so we don't interrupt the presentation of evidence. Generally we'll take an hour or hour and 15 minutes for lunch.

We'll come back in the afternoon. We'll take another mid-afternoon break of five or ten minutes around 2:30 or 3:00. And then we'll conclude each day at 5:00. I want to especially get you out of here by 5:00 today since this is the first day.

There may be days where we might go a little past 5:00 if it's appropriate to do so to avoid interrupting the presentation of a witness or something. But generally we'll be out of here by 5:00 or not much after each day.

When we take these breaks, as I've already told you, you're to go back in your jury room. You can use the refrigerator. If you want to bring lunch, feel free to bring it and leave it in there.

When we take these breaks, you'll be able to leave the jury room, obviously, and leave the courthouse. As I think I mentioned yesterday, I prefer that when you're back in the courthouse you come back to the jury room rather than to be

out in the halls downstairs or upstairs.

Make sure you've got your sticker on when you go out so that no one accidentally approaches you and doesn't realize you're a juror. Obviously, there are a lot of people on both sides, legal staff and others. So I want to make sure that they can tell you're jurors. Also make sure that you have your sticker.

So when we come back after -- we'll come back at 1:30. That's a little more than an hour today to give you a little more extra time.

I don't know how familiar you folks are with downtown Huntington. And I assume you've worked out with the Clerk's Office recommendations about where to park. If you have a problem with parking, let them know downstairs and they'll help.

There are a number of places that you can walk to from here if you want to, or if you want to drive there are places. So the main street out in front of the building here is Fifth Avenue. As you go toward the river on Fourth Avenue and Ninth Street is the plaza walkway. It's just down on this end.

If you go down that plaza, which you'll see when you go out of the building, if you walk down there that takes you to Fourth Avenue. There are several restaurants on Fourth Avenue. There's a Schlotzsky's. There's the Bodega which

is right on the corner.

On the other side of Ninth Street and Fourth Avenue there's a Rio Grande. There may be others.

On over on Third Avenue you've got a bunch of choices. If you've gone down Ninth Street on the plaza, when you get over to Third Avenue if you go to the left there is a Backyard Pizza. There's The Peddler. There's a Thai, or an Asian restaurant. There's Pullman Plaza area or Pullman Square area where there's a Thai restaurant and some other places. There's several restaurants through there. So -- and there's Hall of Fame Cafe that actually has even outdoor seating there.

So those are options. Right over here off of Eighth Street and Sixth Avenue kind of behind us there's a Sheetz which has food. It's pretty fast. So -- or, as I said, you can bring your lunch.

So when you leave the jury room for these breaks, like at lunch if you want to leave anything back here, you can. The courtroom will be kept secure during that time period. So don't feel like you have to lug any stuff with you as you go.

With that, I'll see you back here at 1:30 and we'll start hearing the evidence. You can leave your legal pads either in your chair or in the jury room, whatever you prefer.

You're free to go. I'd like everyone else to remain in the courtroom until the jurors have departed.

Is there anything the parties need to take up with the Court while we're on this break?

MR. CHILDERS: No, Your Honor.

THE COURT: So be ready to present your first witness when we come back.

We stand in recess.

(Recess taken at 12:24 p.m.)

HUNTINGTON, WEST VIRGINIA

WEDNESDAY, OCTOBER 3, 2018, 1:35 P.M.

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(Jury not present.)

THE COURT: All right. Let's bring the jury in.

MR. CHILDERS: Judge, what we have typically done -- we're going to play a video -- is that I will just stand up, introduce who it's going to be, the date of the deposition, and then sit down and let it play.

Is that okay with you?

THE COURT: Yes.

MS. JONES: Yes.

THE COURT: That's fine.

Then are you submitting these on a disk or something, the portions of the video played?

MR. CHILDERS: I thought we were submitting the transcripts; is that correct?

MR. MOSKOW: What we have typically done in the past, Your Honor, is we move these as court exhibits so that -- they don't go to the jury, but the Court has the transcript of what was played.

THE COURT: All right.

MR. CHILDERS: We could give you the video if you'd like that, too.

THE COURT: Well, I'll talk to my court reporter and

the clerk's office and see what we prefer.

MR. CHILDERS: Yes, sir.

THE COURT: All right.

Are these premarked and numbered as plaintiffs' exhibits?

MR. MOSKOW: They're not, Your Honor.

THE COURT: Okay.

MR. MOSKOW: So the parties have negotiated the plays. They've changed up until just a few moments ago. Now they're printed out, and both parties have verified that this is the testimony that will be heard by the jury. And we would move it as a court exhibit or we can add it as a plaintiffs' exhibit or a defense exhibit. It's your pleasure.

(Off-the-record discussion with courtroom deputy.)

THE COURT: Are these already on the list of exhibits?

MR. MOSKOW: They are not, Your Honor.

THE COURT: So they would be supplemental to that?

MR. MOSKOW: That's correct.

THE COURT: All right. That's fine. Let's bring the jury in.

(Jury present.)

THE COURT: All right. We're ready to start with evidence. Plaintiffs may call their first witness.

MR. CHILDERS: Your Honor, as promised, we have video to play for the jury, our first witness. This is Dr. Jeffrey

Friedman. He was the area therapeutic head for cardiovascular for the company Boehringer Ingelheim at the time Pradaxa was developed.

THE COURT: All right. You may play it.

MR. MOSKOW: We just have a technical issue. It's not showing up there.

(Off the record.)

THE COURT: Could you hear that all right to start with? All right. Go ahead and see if it's working.

JEFFREY FRIEDMAN, M.D., PLAINTIFFS' WITNESS,

September 2013 videotaped deposition played.)

(Videotaped deposition paused.)

THE COURT: All right. Ladies and Gentlemen, we're about halfway through this. I know this is difficult. I want to take about a two-minute break here, let you stand up, stretch for a minute if you like, and then we'll resume.

And I'd like counsel to follow this pattern on subsequent video depositions. I don't know how long these are, but my sense is for most of us about 30 minutes at a time would be good, and then maybe if we could have just a minute or two. And I'll let you all decide when and where you would like to break if it's your witness.

So stand up if you want and stretch a minute. You don't have to, but we'll take a second.

(Off the record.)

THE COURT: All right. Let's get started again.

And also let me tell everyone in the courtroom, my clerk just reminded me that at 2:18 today, there's a test of the national alert system. And so if your phone is on, wherever it might be, you're going to get an alert from President Trump.

So I know that jurors don't have their phones. If anybody else happens to, you probably need to power it off completely. I don't know that it will come over anything else, but we'll just see. So you have to power the device off. You can't avoid it otherwise.

All right. Let's get started again.

JEFFREY FRIEDMAN, M.D., PLAINTIFFS' WITNESS,

September 2013 videotaped deposition played.)

MR. CHILDERS: Your Honor, that's the end of the plaintiffs' play.

THE COURT: All right.

MR. CHILDERS: If you want to take a quick break, I think the defense has --

THE COURT: All right. And how long is your portion?

MS. JONES: It's about 30 minutes, Your Honor.

THE COURT: All right. We'll take a brief recess. You can retire to the jury room for a few minutes, and then we'll start back with the rest of this deposition.

(Jury not present.)

(Off-the-record discussion with counsel.)

MR. MOSKOW: Your Honor, if I may.

THE COURT: Yes.

MR. MOSKOW: Plaintiff moves Trial Exhibit 93, 1075, 288 --

THE COURT: Hold on. Let's go slowly.

MR. MOSKOW: I can give the list if that would be more helpful.

THE COURT: Well --

MR. MOSKOW: We've exchanged.

THE COURT: Okay. Any objection to the exhibits listed being admitted?

MS. JONES: No, Your Honor.

THE COURT: They're each admitted.

All right. You want to go ahead and be setting up whatever you all need to do?

MS. JONES: I think we're ready, Your Honor. We just have to press the button. Our tech person is set up.

THE COURT: All right. Why don't you see if they're ready.

(Off the record.)

(Jury present.)

THE COURT: All right. Be seated.

Now the defense is going to play its portion of their questioning of Dr. Friedman; is that correct?

MS. JONES: That's correct, Your Honor.

THE COURT: You may proceed.

And this is about how long you said?

MS. JONES: It's about 30 minutes, Your Honor.

THE COURT: Fine.

(JEFFREY FRIEDMAN, M.D., PLAINTIFFS' WITNESS, September 2013 videotaped deposition played.)

MS. JONES: That's the conclusion of the defense play, Your Honor.

THE COURT: All right. That concludes the deposition.

Ready to call your next witness?

MR. CHILDERS: We might want to take a short break before we call --

THE COURT: All right. How long will it take you to set this next one up?

MR. CHILDERS: Just a couple minutes.

THE COURT: Well, let's go ahead. If you want to stand up, stretch, move about, feel free to do so.

(Off the record.)

THE COURT: All right.

MR. CHILDERS: As you heard, the next witness is Michele Kliewer. She was the regulatory affairs employee for Boehringer Ingelheim in the United States who had direct interaction with the FDA.

This is a shorter play. I believe ours is about 35

minutes total. We will play that, stop, and then the defense has a play. This particular portion of the deposition was taken in 2014.

THE COURT: All right.

MICHELLE KLIEWER, PLAINTIFFS' WITNESS,

April 2014 videotaped deposition played.)

MR. CHILDERS: That's the end of plaintiffs' play for this portion of the deposition.

THE COURT: All right. And does the defense intend to offer its examination of this witness?

MS. JONES: We do, Your Honor. For the 2014 deposition, we have about 12 and a half minutes. We could either do a stretch now or we could go ahead and do the 12 and a half minutes.

THE COURT: Let's go ahead.

MS. JONES: Okay.

THE COURT: If you want to stand up while they reset it, go ahead.

MS. JONES: I apologize, Your Honor. We have a little bit of a glitch that we're fixing.

THE COURT: That's okay. I understand.

MICHELLE KLIEWER, PLAINTIFFS' WITNESS,

April 2014 videotaped deposition played.)

MS. JONES: That's the conclusion of the defense play for the 2014 deposition of Ms. Kliewer.

THE COURT: All right. Thank you.

All right. What do you have next?

MR. CHILDERS: I would suggest we take a short break. We have -- she was redeposed in 2017. We have about a 10-minute play for that. I think the defense's play is a little longer, 20 minutes.

THE COURT: All right. We're going to take about a 10-minute recess. When we get back out, we can finish this in about half an hour?

MR. CHILDERS: Yes, Your Honor.

THE COURT: All right. We'll take about a five or 10-minute recess. You may retire to the jury room.

(Recess taken at 4:18 p.m.)

(Jury not present.)

THE COURT: All right. Are we ready to bring the jury in?

MR. CHILDERS: Sorry.

(Off the record.)

THE COURT: All right. Let's bring the jury out.

THE COURT SECURITY OFFICER: Yes, sir.

(Jury present.)

THE COURT: All right. Call your next witness.

MR. CHILDERS: Your Honor, this is the same witness, Ms. Kliewer, but this was a deposition that was taken in 2017.

THE COURT: All right.

MICHELLE KLIEWER, PLAINTIFFS' WITNESS,

June 2017 videotaped deposition played.)

MR. CHILDERS: That's the end of our play, Your Honor.

THE COURT: All right.

MS. JONES: Your Honor, we have about a 20-minute play from the same 2017 deposition.

THE COURT: You may proceed.

MICHELLE KLIEWER, PLAINTIFFS' WITNESS,

June 2017 videotaped deposition played.)

MS. JONES: Your Honor, that is the conclusion of the defense play for Ms. Kliewer's 2017 deposition, and I believe that's the conclusion of that witness.

THE COURT: All right. Fine. So we'll adjourn for the day.

I know I asked about this yesterday, and several of you have pretty long drives. Are you comfortable trying to start at 9:00, a little bit -- that's okay? All right. Most of you are shaking your head.

So I'll ask you to be back here at 9:00 in the morning. As I've told you before, come directly into the conference room here. We'll wait for you all to be here before we begin, of course.

Remember my instructions. Don't discuss the case with anyone. Don't try to do any research or investigation into any of these matters. And we will see you back here tomorrow

with a fresh mind.

Is there anything the parties need us to do before they leave today? If not, I'll let the jury out first, and then you folks are free to go. See you back here -- be ready to go at 9:00 with your next witness.

You can leave the pads on your seat, if you like, or take them with you, whatever you prefer.

MR. CHILDERS: Thank you, Judge.

MR. MOSKOW: Thank you.

(Proceedings were adjourned at 5:05 p.m.)

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CERTIFICATION:

We, Kathy L. Swinhart, CSR, and Lisa A. Cook, RPR-RMR-CRR-FCRR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter as reported on October 3, 2018.

October 3, 2018
DATE

/s/ Kathy L. Swinhart
KATHY L. SWINHART, CSR

/s/ Lisa A. Cook
LISA A. COOK, RPR-RMR-CRR-FCRR